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**“Doing Well”:  
an initiative to improve depression care**

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**A Thesis Submitted for the Degree of Doctor of Medicine  
to the Faculty of Medicine, University Of Glasgow, based on research  
conducted from Dykebar Hospital, Paisley.**

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# Abstract

## **Aim**

The aim of this thesis was to describe the service use, clinical outcomes and prescribing change associated with the implementation of a complex intervention designed to improve care for people with depression in a primary care setting.

## **Background**

Health systems have limited capacity to provide appropriate psychological and pharmacological treatments for people with depression. Although guidance on the treatment of depression in primary care in the UK was clarified by the National Institute for Clinical Excellence (NICE) in 2004, it is generally acknowledged that the current diagnostic classification of depression is not satisfactory.

Antidepressant prescriptions have continued to rise in Scotland since the mid-1990s, even though there is no indication that the incidence or prevalence of depression is increasing. There is limited access to psychological therapies. Health services have not implemented consistent packages or systems of care in order to provide adequately for patient needs. Although the welfare of staff is critical to their therapeutic engagement with patients, this is rarely an explicit focus of health systems design.

## **Method**

This thesis describes an observational study examining the implementation of a complex intervention to improve depression care called “Doing Well”. The intervention was based in 14 General Practices in Renfrewshire, a mixed urban-rural area in Scotland. The catchment population for the study was 76,000 people. A small team of clinicians implemented a

programme for people with low mood, depression and adjustment disorder, based in primary care.

This programme incorporated a number of changes to standard mental health care, including the following: no “severity threshold” for referral to secondary care; the routine use of an objective measure of depression severity with continuous outcome monitoring; a paperless clinical record; prompt access to guided self-help; prompt “step-up” care to more formal psychological therapy or medical care if indicated; and careful attention to staff training and satisfaction.

### **Findings**

1501 out of 1584 people referred to the programme met inclusion criteria and were included in the study. Three hundred and thirty-two people (22%) did not attend any appointment; 320 (21%) dropped out of treatment after at least one contact. One hundred and ninety-five people (13%) subsequently had their care transferred to other services (of which 43% were to secondary care mental health services), and 654 (44%) of patients completed treatment *per protocol*.

There was good fidelity to the intended model of care, with patients in the “treatment complete” group receiving “brief interventions” of an average of five contacts. These contacts totalled 151 minutes over an average of 103 days of treatment. Referrals from GPs continued at a high and stable level throughout the period of the evaluation. Median waiting times of 15 days were satisfactory.

The mean reduction in PHQ for patients completing treatment was 10.6 points, representing a reduction from baseline of 62%. Seventy-two percent of the treatment complete group showed

a PHQ drop greater or equal than 50%, compared with seven percent in the “disengaged” and ten percent in the “transfer of care” groups.

Doing Well received a lower than expected proportion of referrals from deprived areas, and there was a small negative association between clinical outcome and living in a more deprived area.

Defined daily doses of antidepressants in the practices that had access to the Doing Well clinical intervention increased less rapidly (5.3% between the 12 months to June 2004 and the 12 months to June 2008) than in neighbouring areas or Scotland as a whole (15.8% over the same period). Gross ingredient costs of antidepressants in the Doing Well practices fell more substantially over this period (to 56% of baseline) than in Scotland as a whole (to 65% of baseline). Formulary compliance increased more rapidly in the Renfrewshire area than in a neighbouring area which used the same formulary, but had no contact with Doing Well.

## **Conclusions**

It was feasible to implement and sustain a system of care for depression that was consistent with NICE guidance, including the provision of some form of psychological therapy (including guided self help) for all who needed it. Access to the service was acceptable, and retention within the service compares favourably with equivalent studies in other parts of the UK.

Clinical outcomes were satisfactory, but it was not possible to compare with outcomes in usual care in this observational study. Doing Well practices showed a reduction in the rate of rise of antidepressant use, although did not stop the rise altogether. The implications of this form of “stepped care” for depression for service development are discussed.



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“He that diggeth a pit shall fall into it”... thank you, Ima, for helping me to climb out again.

# 1. Introduction

---

## 1.1 The problem of depression

### 1.1.1 Prevalence

Depression is widely acknowledged to be a major global health problem.

Characterised by low mood, reduced energy and loss of pleasure and interest, the condition is estimated to affect 5.8% of men and 9.5% of women world-wide each year,<sup>1</sup> and 30-40% of people over their lifetime.<sup>2</sup> Depression has been estimated to cause the largest non-fatal global burden of disease, accounting for almost 12% of all years lived with disability, and the fourth largest disease burden worldwide.<sup>3</sup> It has been predicted that depression will be the second greatest contributor to global morbidity by 2020.<sup>4</sup>

Depression is common in the United Kingdom, with a point prevalence of 2.8% for depression alone, and of 9.2% for mixed anxiety and depression.<sup>5</sup> Seventy percent of the suicides in England in 2000 were thought to be related to depression: a total of 2,507 deaths.<sup>6</sup>

The total direct and indirect costs of depression and anxiety in the UK were estimated in 2006 to be £17 billion, or 1½% of GDP.<sup>7</sup> The cost of depression alone in England in 2000 was estimated to be £9 billion, of which £370 million represented direct treatment costs.<sup>6</sup> There were an estimated 109.7 million working days lost due to depression in 2000.<sup>6</sup> Eighteen percent of Scots say they have been diagnosed by a doctor as having depression at some point in their lives.<sup>8</sup>

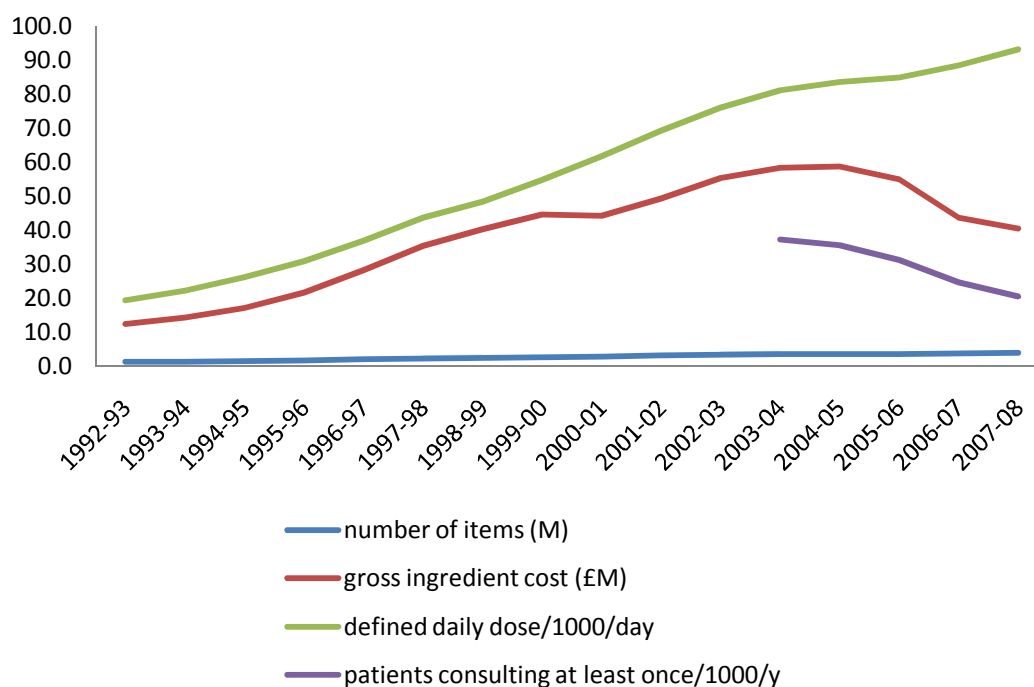
Yet this common condition was considered to be a rarity only fifty years ago. Some authors argue that depression has always been common, but is only now being recognised as an “illness”. Others take a view that the rise of “depression” as a diagnosis is best understood as a social phenomenon, relating variously to social disintegration, the secularisation and commercialisation of culture, or the result of effective marketing of medicines by drug companies.<sup>9</sup> These issues are discussed in greater depth in section 3.2.1 of the Literature Review on page 38. Whichever perspective is correct – and there is likely to be some truth in both views – health services have to provide an effective response for distressed people seeking help for emotional and mood problems.

### *1.1.2 Service use and antidepressant prescribing*

Depression is typically an episodic, recurring disorder, with each episode lasting from a few months to a few years. About 20% of cases result in chronic illness.<sup>10</sup> Depression is a significant reason for people to consult primary care services across the world. A large study surveying primary care attendees in 14 countries<sup>11</sup> found point prevalence rates varying from 2.6% in Japan to 29.5% in Chile; the point prevalence for the UK site (Manchester) was 16.9%.

In Scotland, 38.0 people per 1,000 practice population consulted their GP or practice nurse at least once for depression in the year 2006-7. Depression was the tenth commonest reason for Scots to consult their GP in 2006-7, with an estimated 94.8 consultations per 1,000 practice population for this reason. This represents an estimated 503,700 consultations for Scotland during that period.<sup>12</sup>

Rates of antidepressant prescribing have increased significantly since the early 1990s in Europe<sup>13</sup> and in North America.<sup>14,15</sup> In Scotland, the rate of antidepressant prescribing has increased rapidly, from 28.3 million Defined Daily Doses in 1992/3 to 137.5 million in 2006/7.<sup>16</sup> This increase in antidepressant use has occurred in the absence of any increase in the prevalence and incidence of depression reported changes in depression incidence and prevalence in Scotland, and does not relate to the number of patients consulting for depression, which appears to be falling.<sup>17</sup> This information is summarised in Figure 1-1.



**Figure 1-1: Consultation rates and antidepressant use in Scotland for the period 1992-2008.** Blue line shows number of antidepressant items dispensed in millions;<sup>18</sup> green line shows mean Defined Daily Doses of antidepressants prescribed per thousand population per day;<sup>18</sup> red line shows Gross Ingredient Cost of antidepressants in £million per annum;<sup>18</sup> purple lines shows number of patients consulting in primary care for depression at least once in the year per thousand population<sup>19</sup>

Such national and international averages mask widespread variation at a local level.

Data from primary care shows a 27-fold difference in the recorded incidence of depression between Continuous Morbidity Recording (CMR) practices in Scotland, and referral rates from primary care to specialist mental health services vary 9-fold.<sup>20</sup>

Antidepressant prescribing also varies significantly, with a 4.6-fold ratio between the highest and lowest prescriber deciles in Scotland (after adjustment for age and gender differences in the practice populations and removing the outliers). About half of this variation can be explained or understood, as will be discussed in section 6.5.1.<sup>21</sup>

Deprivation has a strong influence on the presentation of mental health problems in primary care, and socio-economic deprivation in Scotland is concentrated in the NHS Greater Glasgow & Clyde area. An estimated 11.7% of the population of Greater Glasgow and Clyde have mental health problems in the least deprived decile of the population, but this proportion rises to 19% in the most deprived decile.

Antidepressant prescriptions are significantly higher in deprived compared to affluent practices,<sup>22</sup> and deprivation is the factor that explains the largest amount of variation in prescribing.<sup>21</sup>

## 1.2 Health service responses to depression in Scotland

This section provides a brief overview of the organisation of health services in Scotland during the period covered by this study (July 2004 to October 2006), and is intended for international readers not familiar with the Scottish health system.

Most mental health services in Scotland are provided by the National Health Service (NHS); a minority of services are provided by the private sector, or managed by other agencies such as the voluntary sector and local authorities. The Cabinet Secretary for Health and Well Being is responsible for the Scottish Government Health Department and for the NHS in Scotland.

Provision of healthcare in the NHS is the responsibility of 14 geographically-based NHS Boards and a number of National Special Health Boards. The geographically-based boards have responsibility for the delivery of NHS mental health services in primary and secondary care for their areas. “Special” Health Boards charged with health promotion (Health Scotland) and professional education for NHS staff (NHS Education Scotland) work with NHS Quality Improvement Scotland to promote health, prevent illness, and provide quality care through a well-trained workforce.

The Scottish NHS is characterised by coordinated responsibility for the health care of a defined population, subject to democratic oversight. This is unusual in other health systems. Although superficially similar to Health Care Organisations (HCOs) in the United States, Health Boards in Scotland have relatively stable populations, are not for profit and only rarely subcontract out mental health care.<sup>23</sup> The NHS in England has developed differently to that in Scotland since control of health was devolved to the Scottish Parliament in 1999. The Scottish system has not been exposed to



“marketisation” of management systems such as foundation hospitals or “payments by results”.<sup>24</sup>

NHS agencies work jointly with other public bodies to promote health and provide quality care. Local Government has a duty to provide community care services to people with mental health problems, and the 2003 Mental Health Act also requires them to promote wellbeing and social inclusion for this group. This includes not just direct social care services, but also the provision of education, leisure services and housing.

Community Health Partnerships are subdivisions of Health Boards in Scotland, and are responsible for the delivery of local NHS and joint services. They are typically co-terminous with council areas, and provide primary care and community-based mental health services (as well as other health services) for those areas.

Eighty to ninety percent of people with depression are managed entirely within primary care.<sup>25,26</sup> The average practice size for general practices in Greater Glasgow & Clyde is 4,250 patients. A practice of this size will typically be staffed by three general practitioners and two practice nurses, with two attached district nurses and one attached health visitor. Eighty-nine percent of practice populations live within 2km of their practice.<sup>22</sup>

There are on average 7 GPs per 10,000 population in Scotland. This ratio is not strongly influenced by deprivation, meaning that deprived areas have relatively fewer GPs in relation to need. There has been little change in the numbers of GPs working in Greater Glasgow and Clyde over the last 10 years.<sup>22</sup>

The organisation of secondary care mental health services varies across Health Boards in Scotland, but are based on services for adults (services for 18-65 year-olds are referred to as “General Adult Psychiatry”), older adults (65 years and older) and children and young people. Specialist services provide psychiatric services for mentally-ill offenders, people with learning disabilities, and people with substance misuse problems.

General Adult mental health services are typically based on the Community Mental Health Team (CMHT). Access to such teams is usually by GP referral. The teams are multidisciplinary and usually include psychiatrists, community psychiatric nurses, psychologists, occupational therapists, social workers and support workers.

Pharmacists often work in or alongside teams. The numbers of psychiatrists employed in General Adult Psychiatry increased by 40% between 1996 and 2006, from 725.7 to 1,013 whole-time equivalents.<sup>27</sup> Equivalent figures are not available for nursing and other staff, but there were 8,428 registered and 4,148 unregistered mental health nurses working in Scotland in 2005-6, and the number of nurses in all clinical specialities increased by 5% between 2003 and 2006.<sup>28</sup>

Specialist teams have been developed in some areas to work more closely with primary care, to provide services to people experiencing acute mental health crises, to “assertively outreach” to people with the most severe mental illnesses like schizophrenia, and to provide early intervention for people experiencing the onset of psychotic illness.

Most services “tier” their delivery of psychological therapies according to the general model set out in more detail in section 3.2.3. At the lowest tier, services are accessible to the public without a referral. For example, this level would include information

leaflets available through GP surgeries and other health and social care locations, “bibliotherapy” reading schemes available through libraries or GPs, large-scale open-access “psycho-educational” groups, and access to online therapeutic resources.

A range of “low intensity” interventions are available in some areas at a primary care level by GP referral, including (for example) counselling, solution-focused problem solving, supported self help and structured anxiety management groups. These interventions are intended to support people with mild mental health problems, and typically take place over two to six sessions. Such services are often provided by secondary care practitioners working in “Primary Care Mental Health Teams”. Policy in the NHS in England has supported the development of specialist primary care mental health workers since 2000.<sup>29</sup>

More intensive forms of treatment are usually based in secondary care, and involve the provision of psychiatric input and a range of psychological therapies, including cognitive behavioural therapy (CBT), interpersonal therapy and psychodynamic psychotherapy. This kind of care requires specialist input, and typically occupies six to sixteen sessions for “protocol-based” therapies like cognitive behavioural therapy and interpersonal therapy. Psychodynamic psychotherapy is often of far longer duration and is accessed by a relatively small number of people, in part because such treatments are resource-intensive.

Specialist interventions may also be accessed through secondary care and have been developed to treat specific problems (e.g. eating and personality disorders, substance misuse) or to support individuals with very complex or treatment-resistant problems.<sup>30</sup>

A critical issue in the provision of psychological therapies at all levels of skill or intensity is the requirement for staff to be adequately trained, accredited and supervised in their practice. At the higher tiers of care, staff typically require specialist training and accreditation. At more basic levels of intervention, practitioners may need only minimal training, though usually still require some supervision.

Voluntary sector organisations provide a range of support and treatment services for people with mental health problems. Many of these functions are directly commissioned and funded by the NHS, local authorities or Community Health Partnerships. For example, Renfrewshire Community Health Partnership funds the voluntary organisation Renfrewshire Association for Mental Health to provide a telephone-based crisis counselling service called “FIRST Crisis” and to deliver counselling services to local GP practices.

### 1.3 Policy context

The Scottish Government has responsibility for running the NHS in Scotland (the equivalent functions were carried out by the Scottish Office until 2000, and by the Scottish Executive until 2007).

In 1997, a “Framework for Mental Health Services in Scotland”<sup>31</sup> was published by the Scottish Office Health Department. The document described detailed “service profiles” that sought to promote better coordination between health and social services in the planning, commissioning and provision of integrated mental health services. Building on this work, “Towards a Healthier Scotland - A White Paper on Health”<sup>32</sup> proposed that mental health be a “a leading priority for the NHS in Scotland”.

“Our National Health: a plan for action, a plan for change”<sup>33</sup> included mental health as one of three clinical priorities in 2000. It also made a commitment to a national anti-stigma campaign, the promotion of mental wellbeing and a national framework to reduce suicides in Scotland.

The Centre for Change and Innovation was established in November 2002 in the then Scottish Executive Health Department, in order to spread good practice and to increase the capacity of the NHS in Scotland for sustainable service improvement. In addition to its depression care initiative (as part of the “Doing Well by People with Depression” programme), the Centre for Change and Innovation supported national improvement programmes for Outpatients, Primary Care, Cancer Services, Unscheduled Care, Eye Care and Diagnostics. The Centre sought to bring about improvement with the dissemination of quality improvement learning materials,

examples of national and international good practice in clinical and service redesign, and the encouragement of flexible and innovative ways of working.

“Improving Health in Scotland: the Challenge”<sup>34</sup> focussed on the public health dimension to mental and other health problems, and committed the Scottish Executive to establish four actions to promote public mental health. These included the establishment of a “National Programme for Improving Mental Health and Well-being”, and ongoing support for programmes to reduce stigma and suicide between 2003 and 2006.

The Mental Health (Care and Treatment)(Scotland) Act 2003<sup>35</sup> came into effect in October 2005. The legislation was founded on a set of principles, including the importance of patient participation, non-discrimination and informed choice in treatment. Although most relevant to people with severe mental illness, the 2003 Act also emphasised the need for local authorities to provide “services which are designed to promote the well-being and social development” of people who have or have had a mental disorder. This provision includes services for people with depression.

In 2005, “Delivering for Health”<sup>36</sup> made a commitment to “accelerate improvements in mental health services”, building on the earlier Framework for Mental Health in Scotland. This initiative was followed in 2006 by a national Mental Health Delivery Plan called “Delivering for Mental Health”.<sup>37</sup> The plan included three targets and 14 commitments aimed at improving a range of services provided by the NHS and its partners. The plan committed Quality Improvement Scotland to preparing integrated care pathways for depression and four other conditions (schizophrenia, bipolar disorder, borderline personality disorder and dementia).

The Quality and Outcomes Framework is a system of paying practices for providing specified levels of quality that are measured using detailed, evidence-based indicators. In 2006, the framework was amended to include depression as a clinical indicator for the first time. Indicator DEP2 measures the “percentage of patients who have had an assessment of the severity [of depression] at the outset of treatment”.<sup>38</sup>

The high prevalence of depression, the clinical burden of depressive symptoms, and the economic cost to the NHS and wider society were part of the rationale for introducing a quality measure related to depression treatment.<sup>38</sup> The Quality and Outcomes Framework references the British Association for Psychopharmacology guidance about not prescribing for mild depression,<sup>39</sup> and cites Kendrick<sup>40</sup> in support of the use of an objective measure of depression severity to guide antidepressant and other treatment choices.

In summary, the system of health care in Scotland is characterised by universality, democratic oversight, professional responsibility and a commitment to quality, to integration and to health promotion. Although financial incentives have been used to influence GP behaviour, overt commercial activity in the NHS is minimal, and perverse financial incentives are slight. However there may be a lack of coordination between primary and secondary care, who are “separated by budget, by organisation, by culture, by incentives and by disincentives”.<sup>23</sup>

## 1.4 Doing Well

The “Centre for Change and Innovation” in the Scottish Executive Health Department established the “Doing Well by People with Depression” initiative in 2004 in response to strategic concerns about the rising use of antidepressant drugs, and a perceived need to ensure that an appropriate range of treatment strategies were available to people with depression. In May 2002, the Project Manager for the Improving Mental Health Information Project for the Information and Statistics Division presented data showing that the Scotland prescribed 20% more antidepressants per head than England, and at 40% greater cost.<sup>41</sup>

In a joint letter to Health Boards in May 2003, June Andrews (Head of the Centre for Change and Innovation) and David Bolger (Head of the Mental Health Division in the Health Department of the Scottish Executive) outlined why the Health Department had chosen to “redesign services for people with depression”.<sup>42</sup>

“Depression is common, costly and treatable, but in Scotland timely and local access to the full range of interventions and supports is not universal, even where there is good evidence of effectiveness. The issue is not just one of resources, but also the way we manage, communicate and share information.”

The letter went on to describe a “Programme Proposal” which took “a whole systems approach to develop capacity” and sought to make best use of resources by the following actions:



- “Building increased capacity for self-help in order to meet the needs of those with mild depressive disorders and to provide support through the pathway of care.
- Building increased capacity for psychological interventions in primary care thereby offering the potential to reduce some of the current pressures on secondary services.
- Improving assessment of depressive symptoms and associated problems to ensure an agreed understanding of user need with users and carers, together with the sequence of treatments and supports that would be effective, including all of a user’s needs and for people with particular needs.
- Improving access to a range of services and supports within local communities by the creation and active management of networked pathways of care.”

These actions were intended to achieve the following benefits: “Improved wellbeing; improved access and waiting times; more efficient use of resources; improved integration of services across existing boundaries”.

Local development projects were initially selected from seven NHS board areas (Argyll and Clyde, Dumfries and Galloway, Borders, Greater Glasgow, Ayrshire and Arran, Grampian and Lanarkshire). These projects examined approaches to learning and self help, access to psychological interventions, the assessment of depressive symptoms and associated problems and the development of pathways through services and supports.

A national evaluation team was established to monitor the outcomes of the programme and included input from the Universities of Glasgow and Edinburgh and the Scottish Development Centre for Mental Health.

The programme described in this thesis was the project that was established in the NHS Argyll & Clyde area as part of the “Doing Well by People with Depression” initiative. The Renfrewshire project – which became known as the “Doing Well” programme – was set up to use the best available evidence to implement a major reform of service delivery systems and clinical practice. These changes were intended to:

- provide cost-effective, evidence-based care of good quality for people with depression at all levels of severity who present to their GP
- support psychological approaches to treatment, while rationalising antidepressant drug use
- provide adequate clinical capacity to cope with the high need and demand for depression care in the catchment population

A significant redesign was required to provide the new service. The following changes were particularly significant:

- there was no “severity threshold” for referral to the new service
- a paperless referral and record-keeping system was introduced, networked between primary and secondary care
- all patients were seen in their local GP surgery, with clinicians trained, managed and supervised by secondary care

- depression severity was assessed at every contact using a standard depression measure; this measure was used to guide the type and intensity of treatment
- the introduction of some form of psychological intervention for all participants, including guided self-help
- an emphasis on brief interventions, with transfer to secondary care where more intensive or prolonged treatments were required
- careful attention to the wellbeing and professional development of "Doing Well" staff

These service changes are described in more detail in Chapter Four ("Methods") and more details of the rationale for introducing them are provided in the Literature Review in Chapter Three.

## 2. Aims

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The aim of the work reported in this thesis was to conduct a limited evaluation of the Doing Well initiative for people with depression presenting to their general practitioner in Renfrewshire between July 2004 and October 2006. The overall hypothesis was that the implementation of Doing Well would lead to changes in prescribing practice and in other aspects of care.

This thesis therefore has the following objectives:

- To evaluate the capacity of the redesigned “service delivery system” to meet the needs of people with depression in a defined catchment population.
- To evaluate clinical outcomes associated with Doing Well. The main clinical outcome measure was changes in score on the Personal Health Questionnaire (PHQ), a self-complete measure of depression.
- To evaluate prescribing change associated with the programme. This included analysis of changes in the number (Defined Daily Doses), cost (Gross Ingredient Cost) and type (proportion of prescribing in keeping with local formulary recommendations) of antidepressants prescribed. Evaluation included comparisons over time as well as with local and national comparators.

## 3. Literature Review

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### 3.1 Introduction

Section 3.2 examines the assumptions and definitions that underpin the organisation of depression care. Although these conceptual issues may not play a noticeable part in the day-to-day decisions made by clinicians and managers, they nonetheless set the context for routine practice, and will have a significant influence on the care that patients receive. To avoid duplication, this literature review includes material that influenced the development and implementation of *Doing Well* during the years reported in this study (2004-6). More recent work has been included in the discussion.

Sections 3.2.1 (*What is depression?*) to 3.2.3 (*How do services organise their response to depression?*) set out some of the issues that arise when seeking to define depression. These include the natural history of depression, the health service response to it, and the consequences of a diagnosis of depression for patients.

The chapter goes on to discuss the use of antidepressants (section 3.3), psychological therapies (section 3.4) and self-management (section 3.5) as components of the care for depression that is provided in the NHS.

Section 3.6 (*Depression: management in practice*) steps back from everyday clinical practice to consider how service improvement might be able to tackle some of the problems in care delivery identified in Section 3.6.2 (*Problems in current service provision*). This is an important section, since it informs not only how we should seek to understand the question “did *Doing Well* improve clinical care?”, but also to shed

some light on the organisational mechanisms which may underlie the effective implementation of change in health systems.

Some “generic” service improvement techniques are reviewed, before considering in Section 3.7.2 (*Models of service redesign in depression*) how these have been packaged together in mental health care to provide complex interventions for depression. This section will particularly focus on the need to acknowledge and respond to the “complexity” that characterises health systems. Some models of service redesign are described, before a summary of trials of that have evaluated different models of enhanced care for depression.

## 3.2 Depression: concepts and definitions

### 3.2.1 *What is depression?*

“Depressive” symptoms have been described with striking consistency for 2,500 years.<sup>43</sup> Since the first medical texts in ancient Greece, depression has been recognised as a syndrome characterised by low mood (including lack of pleasure, despair, anxiety, and suicidal thinking) and accompanied by bodily and behaviour changes (such as disturbance in appetite, sleep, self-care and social activity). Although successive generations of clinicians and scholars have struggled to define the boundaries of this condition, there has been near-unanimity in the recognition of two broad categories: “normal sadness” and “sadness without cause”.<sup>43</sup>

This conceptual dichotomy was evident through much of the 20<sup>th</sup> Century, finding expression in distinctions between “endogenous and reactive” depression, “primary and secondary” depression or “depressive disease” and “depression spectrum disease”.<sup>44</sup>

Until the mid-twentieth century, “anxiety” and “neurosis” were commonly described traits, but “depression” was diagnosed for only a tiny percentage of the population.<sup>45</sup> When antidepressants were first developed in the 1950s, initial estimates suggested that no more than 50 to 100 people per million suffered from the kind of depression that these new drugs would treat. These estimates wildly underestimated the growth in antidepressant use, which still continues to increase.

What has caused this expansion in pharmacological treatment for depression? It may be that doctors are now better able to recognise and treat a valid clinical syndrome that has tended to be neglected in the past. Alternatively, we may have

inappropriately redrawn the boundaries of illness so that the clinical syndrome of “depression” has come to include the normal experience of sadness, worry and other forms of human distress.

Some allege that doctors and the pharmaceutical industry created a “new” disease of depression to benefit from new drug treatments;<sup>46</sup> or that a secular, fragmented and commercialised society has unrealistic expectations of happiness;<sup>47</sup> or that antidepressants and other psychotropic drugs are used to make intolerable social conditions bearable.

This thesis does not seek to answer such political and philosophical questions.

Nonetheless, there is a consensus in the scientific literature (discussed later in this section) that our current diagnostic classification of mood disorder is unsatisfactory.

Uncertainty about the boundaries of depression necessarily raises questions about the identification of appropriate forms of treatment, both psychological and pharmacological. This uncertainty and unease about our understanding of depression is shared by the general public, especially the large subset of the population who develop low mood each year.

The Doing Well patients who were the subjects of this thesis sought help to understand why they had become distressed, because they had to decide how to respond to these problems. Should they take medicine, pursue a course of therapy, both of these options, or none at all? This section briefly outlines the changing context in which those decisions might be framed.

A critical change in our conceptualisation of depression took place during the development of psychiatric classification systems from the mid-1970s. The current



versions of the International Classification of Diseases (ICD-10)<sup>48</sup> and the Diagnostic and Statistical Manual (DSM IV)<sup>49</sup> are based on a syndrome termed “depressive episode” in ICD-10 and “major depressive episode” in DSM IV. These syndromes are defined by a set of “depressive symptoms”, and a requirement that these should have been present for more than two weeks. Depression is further categorised in relation to mild, moderate and severe grades of illness, and between single and recurrent episodes. Both systems also identify a “somatic syndrome” (ICD-10), or depression “with melancholic features” (DSM IV) that is perhaps closest to older concepts of “endogenous” depression or “melancholia”.

Crucially, contemporary classifications make a diagnosis on the basis of symptoms only, without reference to underlying theories of causation. There is, however, one important exception. Both ICD and DSM exempt a diagnosis of depression where, according to DSM, “the symptoms are not better accounted for by bereavement”. Horwitz and Wakefield point out<sup>43</sup> that bereavement is a form of “sadness *with* cause”, and therefore that its exemption from a diagnosis of illness represents a tacit acknowledgement that “normal sadness” might otherwise be confused with a medical disorder. Should bereavement be the only form of loss to be so recognised, or should other life events (like unemployment, divorce or migration) not also be reasons to exclude the diagnosis of depression?

Freud argued that melancholia might occur as the result of the death of a loved person, but could also be a response to the loss of an “an object of love”, even when “one cannot see clearly what has been lost”.<sup>50</sup> Psychoanalysts in this tradition consider that the powerful emotions associated with depression and anxiety are, in fact, responses to loss. Rather than focus on specific symptoms, a psychoanalytic

perspective pays heed to (for example) dependence and neediness in relationships; to the re-enactment of earlier developmental difficulties; and to “identification” with the lost person and a range of other defence mechanisms.<sup>51</sup>

Nonetheless, the decision to base psychiatric diagnoses solely on symptoms rather than presumed aetiology has sound practical and theoretical justifications. These were reinforced when an influential paper examining depression in primary care in the UK suggested that the distinction between “endogenous” and “reactive” depression was not relevant to drug treatment decisions.<sup>52</sup>

Profound consequences have arisen from the use of a “symptom-based” classification that largely disregards context, and so does not distinguish between the symptoms of illness and the human expression of “normal” distress. It seems likely that this ontological blind spot has caused the “boundaries of what constitutes depression being expanded relentlessly outward”.<sup>53</sup> Sadness “with cause” is a common phenomenon, so such “diagnostic inflation”<sup>43</sup> has ramifications beyond academia or the clinic.

Clear evidence has emerged of the importance of social factors in the development of low mood. Depression is influenced by poverty,<sup>22,54,55</sup> unemployment,<sup>54,56</sup> separation, divorce,<sup>57, 58</sup> and stressful life events, especially where these are perceived as threatening or humiliating.<sup>59-61</sup> A large, prospective study of an Australian cohort with depression found a high prevalence of associated problems: 40% of subjects with depression reported childhood sexual abuse, 57% reported childhood physical abuse, 42% had at some time been afraid of their partner, and 72% reported a chronic physical condition.<sup>62</sup> Conversely, depressive symptoms remit when there is a fresh start or adjustment to the loss,<sup>58,63,64</sup> especially for people with good social support.<sup>65</sup>

This critique was perhaps anticipated by the authors of ICD-10, in their tentative comments on the limitations of the classification:

“affective disorders are not yet sufficiently understood to allow their classification in a way that is likely to meet with universal approval... the classification presented here is put forward in the hope that it will at least be acceptable, since it was the result of widespread consultation”.

The National Institute of Clinical Excellence guideline on depression summarises the difficulty as follows:

“the most significant limitation is with the concept of depression itself. The view of the Guideline Development Group is that it is too broad and heterogeneous a category, and has limited validity as a basis for effective treatment plans. A focus on symptoms alone is not sufficient because a wide range of biological, psychological and social factors have a significant impact on response to treatment and are not captured by the current diagnostic systems.”<sup>26</sup>

R Philip Snaith, one of the authors of the Hospital Anxiety and Depression Scale,<sup>66</sup> described with a more flamboyant scepticism the range of emotional states that a diagnosis of depression is supposed to encompass: “here are the states of grief at loss, frustration of failed aspiration, the gloom of despair, the accidie of disillusion, the demoralisation of the long suffering and the cynical outlook of the pessimist”.<sup>67</sup>

If depression is “an over-inclusive term with a lack of conceptual clarity between symptom, syndrome, episode and illness”<sup>43</sup>, how could it be improved? Although

symptom-counting may be insufficient to distinguish an illness called “depression” from other forms of human distress, it is nonetheless necessary. Symptoms remain at the core of the psychiatric understanding of low mood: since they describe the patient’s current experience, they cannot be removed from a diagnostic assessment. However they may make more sense if complemented by consideration of the temporal and contextual relationship to loss events.

Horowitz & Wakefield propose three characteristics of “normal” loss responses: they emerge after specific environmental triggers, they are proportionate in intensity to the loss, and they end either as the loss situation ends, or as natural coping mechanisms allow the individual to readjust to their new situation.<sup>43</sup>

ICD-10 and DSMIV do recognise time course and context in relation to emotional distress, but relate them to “adjustment disorder” rather than “depression”.

“Adjustment disorder” is defined in DSM as “the development of emotional or behavioural symptoms in response to an identifiable stressor occurring within three months of the onset of the stressor”. This causes “marked distress that is in excess of what would be expected from exposure to the stressor or significant impairment in social or occupational functioning”.

Casey *et al* argue that adjustment disorder would be a better description for much of the low mood that presents to primary care.<sup>68</sup> This diagnosis implicitly acknowledges the situational context for much distress, and that it tends to remit spontaneously. But both ICD-10 and DSM-IV state that this condition should only be made if criteria for other conditions are not met, meaning that in practice it will be subordinate to other diagnoses. There is a risk that this convention over-estimates the prevalence of depression at the expense of adjustment disorder.

The tension between a reductionist symptom-count and a more holistic appraisal of distress in a personal and social context will be returned to in the discussion. Doing Well sought to deal with the lack of conceptual clarity between symptom, syndrome, episode and illness in ways that are described in section 4.4, on page 133. Doing Well accepted referrals for depression, low mood and adjustment disorder, and responded to each with a careful case formulation and a pragmatic care plan. This will be discussed more fully later in this thesis.

### *3.2.2 What happens to people who become depressed?*

Psychiatrists working in secondary care settings have long recognised that the depressive illnesses they see are often chronic conditions with a poor prognosis. Kraepelin speculated that left untreated, major depressive episodes would tend to last about 6 to 8 months in most cases.<sup>69</sup> Recent studies show that 12% to 40% of depressed inpatients never recover from their illness. Of those who do recover, 60%–90% subsequently relapse over the next 5–10 years, and only 25% of patients never experience a recurrence.<sup>70,71</sup>

By contrast, Posternak<sup>72</sup> found relatively high rates of remission in a cohort of 130 secondary care patients who had previously experienced one depressive episode and subsequently relapsed. Forty-six subjects went on to take drug treatment (with a median time to treatment of 62 weeks). Both groups were followed up six-monthly for five years and annually thereafter. The endpoint was considered to be remission from symptoms, the onset of antidepressant treatment, or the close of the study after 15 years of follow-up. By three months, 38% of the drug-treated and 52% of the

untreated cohort had recovered. The recovery rate decreased rapidly after three months, though still stood at 67% at 6 months for the untreated group. It seems that non-treatment seeking individuals had a better prognosis than those who did seek treatment.

Nonetheless, there is a consensus that people treated in secondary care often experience depression as a chronic disorder. Studies of the long-term outcome of depression in the community and primary care can be difficult to compare, but the natural history of depression in community samples is probably more benign: for this group, depression is more typically a disorder that remits,<sup>73</sup> with overall recurrence rates typically between 30% and 40%. The relationship between treatment and long-term outcome remains unclear.<sup>71</sup>

The findings of community-based studies relevant to the Doing Well programme are summarised below.

Using a community survey, McLeod et al identified a sample of 119 married men and women with major depression according to the Diagnostic Interview Schedule.<sup>74</sup> Forty percent of episodes recovered in less than 5 weeks, and 90% by one year.

In an epidemiological study of 235 women meeting full DSM III-R criteria for major depression, Kendler<sup>75</sup> found that for women whose depression began in the previous year, the median time to recovery was 42 days. One quarter and three quarters of the sample had recovered by 21 and 90 days respectively; 98% had recovered within a year. Seven percent of patients in the sample had experienced depression for more than a year prior to inclusion; including them in the analysis lengthened the time to recovery for the whole group from a median of 42 to 56 days, and more than tripled

the proportion unrecovered by the end of the year. The study did not collect information on treatment received.

The Epidemiologic Catchment Area Program in Baltimore, USA followed up a 1981 baseline cohort of 3,481 respondents with a second assessment 12-15 years later. The 25th, 50th, and 75th percentiles for the duration of 71 first episodes were 4, 12, and 30 weeks respectively. The duration of an episode, and time to an episode-free year, was longer in the first episode than in recurrent episodes.<sup>76</sup>

A longitudinal cohort study of patients with depressive symptoms from 30 metropolitan and rural general practices in Victoria, Australia, found that 22% of the cohort who satisfied criteria for “probable depression” at screening no longer did so around 2 weeks later.<sup>62</sup>

A prospective psychiatric epidemiological survey in the Dutch adult general population found a median duration of major depression of three months, with 50% of patients recovered within three months, 76% within twelve months and 80% at 24 months.<sup>77</sup>

In summary, most studies of depression have been conducted on patients recruited through secondary care, who tend to have low rates of remission and high rates of relapse. By contrast, epidemiological and community-based studies show relatively high rates of remission, including spontaneous remission without treatment. Both the “secondary care” and the “community” cohorts were diagnosed as having depression using valid assessment tools, yet the prognosis for the two groups is markedly different.

This presents a problem for clinicians and service planners. One group (in secondary care) require intensive and sustained treatment to optimise remission and minimise the risk of relapse: while the other may do relatively well with no treatment at all. The effective design and delivery of an appropriate service would depend critically upon the ability to discriminate between these two groups. The following section reviews how services respond to people with depression in the British National Health Service.

### *3.2.3 How do services organise their response to depression?*

Conventional descriptions of access to healthcare in the UK typically relate to the “tiered model” of care proposed by Goldberg and Huxley<sup>78</sup> (Figure 3-1). This model describes 5 “levels” of help-seeking, from relatively widespread psychological morbidity in the general population through to the small numbers of people who receive psychiatric inpatient care. These levels of care are mediated by 3 filters: of help-seeking by the patient, of recognition in primary care and referral to secondary care.



Level	Type of care
Level 5	Psychiatric inpatients
Filter 4	Admission to psychiatric beds
Level 4	Psychiatric patients
Filter 3	Referral
Level 3	Conspicuous psychiatric morbidity/ primary care visitors
Filter 2	recognition
Level 2	psychiatric morbidity/ primary care visitors
Filter 1	Help-seeking
Level 1	Psychiatric morbidity/population

**Figure 3-1: the tiered model of care**

If we accept that different forms of depression have different outcomes and may require different types of care, then the organisation of these “tiers” becomes crucial for effective service delivery. Two aspects are especially important. Firstly, the type of care should be appropriate to the level of severity or complexity of the case. Secondly, the decisions taken at the level of the three filters need to be as well-informed and rational as possible. In fact, health systems have commonly failed to meet these two requirements. Severity and complexity are typically assessed using the subjective judgement of the clinician, rather than using formal measurement tools. The transition between one tier and another is often prolonged and bureaucratic, since

systems are usually constructed around service and professional structures, rather than the needs of the patient.

For example, the 1997 Framework for Mental Health Services in Scotland<sup>31</sup> was based on a 5-tier model that describes the type of help that people should access for mental health problems. It clearly borrows the structure of the Goldberg and Huxley model, with lower tiers of care covering more people, but requiring less skill or intensity in treatment than the higher tiers (Figure 3-2). The tiers are essentially defined by the setting and the input of professionals. Although there is a rough gradient of severity from mild to more severe problems, these are only vaguely defined. Tier one is for “less severe” problems, but severity is not mentioned in tier zero or tier two. The Framework document includes a two-page appendix that seeks to define “severe and enduring” mental illness, but it is difficult to distinguish between the “severe and enduring” problems associated with tier four, and the “severe, persistent and complex” disorders described in tier three. The indications for transition between tiers are therefore not well defined.

Tier	Description of services
Tier 4	This tier is for those with severe and enduring mental health problems and services including day units and highly-specialised inpatient and outpatient care.
Tier 3	A multi-disciplinary team, working in a community mental health team or psychiatry out-patient department. This is a specialised service for people with more severe, persistent and complex disorders. The team might include psychiatrists, community psychiatric nurses, clinical psychologists, occupational therapists and social workers, amongst others.
Tier 2	At this level support and assessments would come from more specialist professionals such as counsellors, primary care mental health workers, and psychologists. Services may be based within primary care. Primary care mental health workers (who may or may not have a clinical background) are a relatively new support service within this tier.
Tier 1	Help at this level would be provided by GPs, other primary care professionals, social workers, and voluntary sector agencies. General advice and treatment for less severe problems would be offered at this tier and referrals can be made to more specialist services as required. Self-help workers would also operate within this tier.
Tier 0	At this level people would be accessing resources within the community to enable them to be able to cope better at home and avoid the need for professional or other interventions at Tier 1

**Figure 3-2: Tiers of care according to the "Framework for Mental Health Services in Scotland"**

The National Institute for Clinical Excellence (NICE) described a "stepped care" model for depression<sup>26</sup>, which has a similar hierarchical structure, but which makes more explicit reference to the need for assessment of severity. Five "steps" in care are proposed (Figure 3-3): step one represents recognition and assessment of depression in primary care. Mild depression (step two) and moderate to severe depression (step three) are managed by the primary care or primary care mental health team.

Treatment resistant or complex depression at step four is managed by specialist teams in secondary care. Severe self-neglect or risk to life at step five is managed either by "intensive home treatment teams" or as an inpatient.

Step	Who is responsible for care?	What is the focus?	What do they do?
Step 5	Inpatient care, intensive home treatment teams	Risk to life, severe self-neglect	Medication, combined treatment, ECT
Step 4	Mental health specialists, including intensive home treatment teams	Treatment-resistant, recurrent, atypical and psychotic depression, and those at significant risk	Medication, complex psychological interventions, combined treatments
Step 3	Primary care team, primary care mental health worker	Moderate or severe depression	Medication, psychological interventions, social support
Step 2	Primary care team, primary care mental health worker	Mild depression	Watchful waiting, guided self-help, computerised CBT, exercise, brief psychological interventions
Step 1	GP, practice nurse	Recognition	Assessment

**Figure 3-3: National Institute for Clinical Excellence "stepped care" model for depression**

This model therefore defines the levels of care in three ways: by the severity of illness, the type of treatment and by the teams or clinicians who could deliver those treatments. The guidance refers to this as a "stepped care" model:

"The stepped-care model of depression draws attention to the different needs that depressed people have – depending on the characteristics of their depression and their personal and social circumstances – and the responses that are required from services. It provides a framework in which to organise the provision of services supporting both patients and carers, and healthcare professionals in identifying and accessing the most effective interventions."<sup>26</sup>

It goes on to say:

“Each step introduces additional interventions; the higher steps assume interventions in the previous step.”

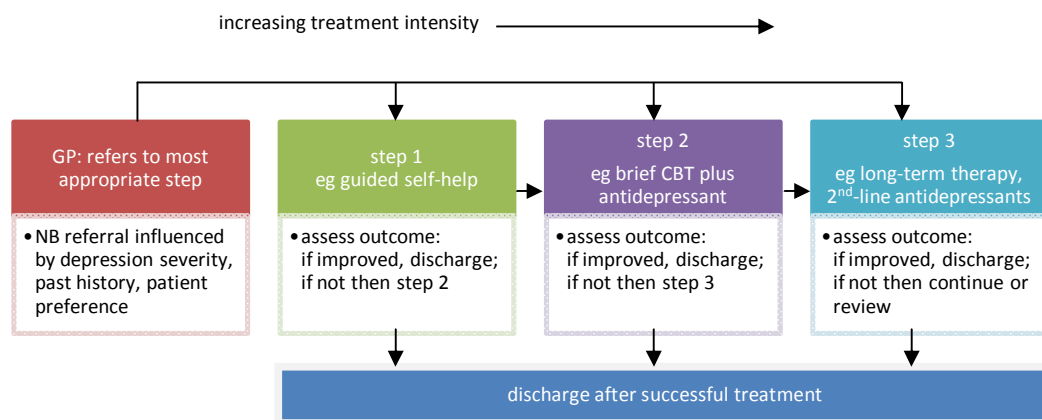
This interpretation of the stepped care model differs significantly from the more sophisticated interpretation of stepped care described by Bower and Gilbody<sup>79</sup>:

“Stepped care is a model of healthcare delivery with two fundamental features. First, the recommended treatment within a stepped care model should be the least restrictive of those currently available, but still likely to provide significant health gain. Second, the stepped care model is self-correcting.”

To “assume interventions in the previous step” contradicts the first feature of the Bower & Gilbody model, in that the “least restrictive” intervention likely to work should be the first to be tried (and not the most basic, as NICE guidance suggests). Secondly, the NICE model does not take account of the critical role played by monitoring and feedback as part of the “self-correcting” requirement to determine the right level of care. For example, non-response needs to be identified promptly if treatments are to be “stepped up”, but the NICE model does not incorporate this critical element in its description.

An alternative to the “tiered” care model can be represented by a more linear model of patient “flow”, which uses feedback about progress to influence treatment

decisions (Figure 3-4).



**Figure 3-4: flow in stepped care (adapted from Bower & Gilbody, 2005)**

Depression severity will typically vary within any one episode of illness. For example, although a patient may present to their GP with mild depression, this may become more severe over time, before remitting in response to treatment. That individual might therefore benefit from intervention at steps one, two, three *and* four, rather than remaining within one category.

Defining care according to categories (of illness severity, staff role and therapeutic intervention) as the NICE model does is therefore problematic. There are extensive areas of overlap between “steps” and the optimal combination of interventions at any given level is unknown.<sup>80</sup> The kind of “stepped care” model outlined above seeks to overcome these limitations by acknowledging the potential for change within a patient’s experience of an episode of depression. The use of dynamic models of “flow” within healthcare systems influenced the design of the Doing Well service, and will be

discussed in more detail in section 3.7.1, (*Components of health service redesign*). A key component in the successful implementation of such models is to ease the transfer between one part of a service and another. This may be particularly challenging when organising care delivery between primary and secondary care services.

“Collaborative” care aims to support these transitions, “with active collaboration from primary and secondary care in devising a common pathway or ‘ladder’ they can each welcome and work with easily.”<sup>81</sup>

### 3.2.4 *Mental health literacy, stigma and public attitudes*

Patients with acute and chronic health problems benefit when they are involved in their care, and there is some evidence to suggest that this can lead to better use of resources.<sup>82</sup> This section considers some of the factors that may act as barriers not only to seeking professional help, but also to being able to recognise and understand problems with mood when they arise.

This type of knowledge and skill has been termed “health literacy”: the ability to access, understand and use information in ways which promote and maintain good health. Although depression is a very common condition, some members of the public may not share clinical concepts, or have a limited understanding of it when they do. When an Australian sample was asked to identify case vignettes designed to represent depression, only 39% correctly identified depression, with a further 22% of respondents mentioning stress.<sup>83</sup> In a similar exercise conducted in Scotland a decade

later, about three-quarters of a representative sample of the population were able to correctly identify a “depression” case vignette.<sup>84</sup>

Health care professionals are rarely a source of information about mental health problems for the general public. Asked which single source of information had been most influential in forming their impressions of mental health problems, the majority of respondents in a large-scale Scottish survey mentioned either personal contact and experience, or television news and current affairs programmes, with only a small minority (nine percent) mentioning information from clinicians.<sup>84</sup> Nonetheless, when asked who would be the most appropriate source of support for someone with depression, respondents in the Scottish survey suggested a family doctor (63%), a qualified counsellor (43%) or “someone in the family” (53%). Twenty-nine percent of respondents thought a psychiatrist was the most appropriate source of support.

Poor information and a lack of a shared understanding about depression may not prevent help-seeking, so much as redirect it to less conventional sources of help. About one half of the population of European countries have consulted “complementary” or “alternative” medical practitioners (seeking remedies such as homeopathy, Chinese medicines, and reflexology), and many of these people seek help with depression, stress, insomnia and anxiety. In 2005, there were 47,000 complementary and alternative practitioners in the UK, compared with 35,000 GPs.<sup>85</sup>

Evidence suggests that interventions designed to mitigate the effects of low health literacy in general health settings (such as providing information leaflets or patient-focussed websites) can improve knowledge and health behaviour, but work best when used to complement or augment communication with clinicians.<sup>82</sup>



Critics of psychiatric attempts to reduce stigma or “educate” the public have pointed out that the “medical model” of mental illness is not only unproven but contested; furthermore that “the prospect of psychiatrists successfully simply offering ‘the facts’, relies on audiences who will trust them.”<sup>86</sup> An historically fraught relationship between psychiatry and the public means that this trust may not be present.<sup>87</sup>

However the evaluation of a large-scale, multifaceted Australian campaign (“beyondblue”) to improve understanding of depression suggests that people living in the States and Territories that received the programme were more likely to recognise symptoms, to seek help and to accept treatment for depression than people in areas who were not exposed to the campaign.<sup>88</sup>

The problem is not merely a lack of knowledge, but also a question of attitudes. Depression is less stigmatised than other conditions, but a significant minority of respondents in UK surveys nonetheless agree with discriminatory or inaccurate statements about people with depression.<sup>89</sup> For example, a common myth in relation to depression is that it “results from a personality weakness or character flaw, and people who are depressed could just snap out of it if they tried hard enough”.<sup>90</sup> Members of the public may therefore not share professional concepts of what constitutes a mild to moderate psychiatric problem. Many people do not regard the experience of psychosocial distress associated with a range of conditions as an appropriate topic for medical consultation or scrutiny.<sup>91</sup>

In order to seek help, therefore, someone with depression needs to be able to recognise and understand their problems, while resisting stigmatising pressures which militate against disclosure. There is a final step that must be negotiated. Since clinical interactions are governed by social etiquette, consultations can be difficult

encounters for patients. A reluctance to divulge personal information may be an effort to protect their privacy and personal integrity,<sup>92</sup> and therefore act as a final barrier to accessing appropriate care. (The interaction between patient and doctor during consultations about depression is discussed further in section 3.6.1.)

Negotiation through the “tiers” of care is therefore determined not simply by the service response to a “case” of low mood, but instead reflects a more complex relationship between the concerns, information and expectations of the individual in a dynamic interaction with staff working in the health system.

To be effective, services therefore need to take account of the concerns and expectations held not only by individuals, but also by the social context in which they live and work. The diversity of perspectives about low mood and emotional distress mean this is a particular challenge for depression care.

### 3.3 Antidepressants

#### 3.3.1 *The rise in antidepressant use*

Marked increases in antidepressant use have been reported in many Western countries since the early 1990s. Rises in antidepressant use have been reported in Scotland,<sup>17</sup> England,<sup>93</sup> France,<sup>94</sup> Germany,<sup>94</sup> Italy,<sup>95</sup> Holland,<sup>96</sup> Scandinavia,<sup>97</sup> Iceland,<sup>98</sup>, Canada,<sup>15,99</sup> the United States<sup>14</sup> and Australia.<sup>100</sup>

It is difficult to draw clear conclusions from international comparisons, since the situation in each country can be quite distinct. For example, in 2002 more than twice as many Defined Daily Doses (DDDs) of antidepressants per 1,000 inhabitants were consumed in the United Kingdom and France than in Germany.<sup>94</sup> There are several reasons why antidepressant drug use should be lower amongst German people. The prevalence of depression is recognised to be lower (4% in Germany, compared with 9% in France and 10% in the UK). But there is also a high level of herbal antidepressant use in Germany,<sup>94</sup> and people in that country have relatively easy access to psychological therapies.<sup>101</sup> Concerns about adverse effects of SSRIs (suicidality and haemorrhage) by the German regulatory authorities seem to have slowed the uptake of these drugs until recently.<sup>94</sup> By contrast, most of the rise in antidepressant drugs in the UK,<sup>94</sup> the USA,<sup>102</sup> Nordic countries<sup>97</sup> and Iceland<sup>98</sup> relates to an increase in the use of SSRI drugs.

In Canada, antidepressant prescriptions rose 238% between 1981 and 2000,<sup>15</sup> a rise which may have been largely accounted for by a rise in the prevalence (but not incidence) of depression.<sup>99</sup> In the USA, consultations for depression rose by 70% between 1987 and 2001 (representing a relative increase in the number of primary

care rather than psychiatry visits), and over the same period the total antidepressants prescribed increased by 116%.<sup>102</sup> Antidepressant use increased in Iceland by as much as 8.6 times between 1975 and 2000 and 3.9 times between 1989 and 2000. This increase was associated with modest rises (2% per annum) in outpatient service use for depressive disorders.<sup>98</sup>

The number of prescriptions for antidepressants almost trebled in Scotland over the decade to March 2003,<sup>103</sup> yet there was no association between this rise and the incidence or prevalence of depression, consultation rates for depression or levels of psychological morbidity (as measured by the GHQ12) in Scotland between 1995 and 2001.<sup>17,104</sup>

Variation in prescribing rates is recognised in other areas of medicine. For example, in a comparison of 500 GP practices in England, some prescribed as much as 50 times more cholesterol reducing drugs than others,<sup>105</sup> even though the use of such drugs does not involve the kind of socio-cultural or diagnostic complexities influencing practice in depression care.

Antidepressant prescribing varied up to 25-fold in one study in East London.<sup>106</sup> Some of this variation will relate to differences in the prevalence of depression in different areas, and some will relate to the use of “antidepressant” drugs for indications other than depression. Nonetheless, these factors alone do not adequately explain the entire rise in antidepressant prescriptions.

In a large Scottish study of 983 practices by our group, Morrison et al.<sup>21</sup> found a 4.6-fold difference between the first and ninth deciles of antidepressant prescribing, standardised for registered patients’ age and sex composition. A multivariate model

was used to examine factors associated with prescribing. The age–sex standardised rate of limiting long-term illness, practice location in an urban area, and the proportion of female GPs were positively associated with prescribing levels of antidepressants. A higher proportion of patients from minority ethnic groups in the practice, single-handed practices, higher practice list size, practice location in very remote areas, higher GP age, and a higher proportion of GPs born outside the UK were associated with lower antidepressant prescribing levels. These nine factors accounted for half of the observed variation in prescribing rates. No association was found between markers of quality care and antidepressant prescribing. In this study, limiting long-term illness was the most influential factor on variation in antidepressant prescribing levels, and represented a proxy indicator of deprivation.

Significant associations between raised prescribing levels, socio-economic deprivation and limiting long-term illness has been noted for all prescribed drugs<sup>107</sup> and also for antidepressants.<sup>108</sup> A study of 3,044 National Health Service (NHS) patients attending 26 general practitioners in the West of Scotland examined the interactions between deprivation, morbidity, access and consultation behaviour in primary care.<sup>109</sup> The authors found a close association between low socioeconomic status, “multimorbidity” (the number of long-term conditions) and psychological distress. Patients in deprived areas consulted more often for psychological and social problems compared with patients from affluent areas. Consultations for psychosocial problems with patients from deprived areas were more likely to be longer, to be associated with lower patient enablement, and to be more stressful for GPs.

Nobody can say with certainty what the “right” level of antidepressant use for any given population might be. However the following factors could be expected to have an influence on prescribing rates in any given population:

- The incidence and prevalence of depression
- The concepts of depression and psychosocial distress understood by patients
- The proportion of people with depression seeking professional help
- The concepts of depression and psychosocial distress understood by prescribers
- How clinicians recognise and respond to depression in the consultation
- The proportion of people with a diagnosis of depression offered drug treatment
- The dose of antidepressants prescribed
- Acceptance of antidepressant treatment by patients, and concordance with that drug treatment
- The duration of drug treatment
- The proportion of antidepressant drugs used for non-depression indications (such as anxiety, obsessive-compulsive disorder, insomnia, chronic pain, enuresis etc.)
- The availability of non-pharmacological methods of treatment
- The attitude of the GP towards the effectiveness of antidepressants

A recent UK study of 189,851 patients in the UK who experienced their first episode of depression between 1993 and 2005 has shed some light on this issue. The study examined the GP research database, which contains linked anonymised records of over 3 million patients registered in the UK. The majority of antidepressant prescriptions were given as long term treatment or to patients with multiple episodes of depression. Small increases both in the proportion of patients in these groups and in the duration of prescriptions made to such individuals accounted for a near doubling of the total volume of antidepressant prescribing between 1993 and 2005.<sup>110</sup>

This is clearly a complex area, and information is limited. Nonetheless, the extent of the rise in antidepressant use has not prevented some influential observers from drawing broad conclusions relating to the influence of pharmaceutical companies and the readiness of the population and their doctors to “medicalise” problems in everyday living. The UK Parliament Select Committee on Health reported in 2005<sup>111</sup> that:

“The belief that every problem may be solved with medication seems particularly relevant in the context of antidepressants. While we readily accept that antidepressants can be effective medicines and have been successfully used by many patients, it is also clear that SSRIs, in particular, have been over-prescribed to individuals, often with mild forms of depression, who may be distressed by difficult life circumstances. Unhappiness is part of the spectrum of human experience, not a medical condition.

This trend has not been created by the pharmaceutical industry but it has been encouraged by it. The industry has acted, in the words of some witnesses, as a “disease-monger”, with the aim of categorising an increasing

number of individuals as 'abnormal' and thereby requiring [drug] treatment.

This process has led to an unhealthy over-reliance on, and an over-use of, medicines. It also diverts resources and priorities from more significant diseases and health problems.”

This Parliamentary Report is quoted here to emphasise that although clinical research into prescribing practice suggests a complex issue that is only partly understood, politicians may nonetheless come to firm views and express them in strong language. As a Government-funded initiative, visited and reviewed by Ministers from the Scottish Government, Doing Well was careful to acknowledge with policymakers that clinical evidence in this area is often partial or inconclusive.

### *3.3.2 Pharmacological efficacy of antidepressant drugs*

A full review of antidepressant efficacy is beyond the scope of this literature review. Instead, the 2004 NICE good practice guideline on the treatment of depression<sup>26</sup> will be taken as the baseline. Evidence published after the NICE guideline is then briefly reviewed.

#### **3.3.2.1 NICE guidance**

NICE identified 103 studies relating to the drug treatment of depression published between 1983 and 2003, of which 48 were considered to be suitable for inclusion in the review (including a total of 7,460 patients). The guidance acknowledged some significant limitations to the analysis. The trials included were typically short-term, with only 16 trials of eight weeks or longer (range between four and 24 weeks long, with a mean of 6.75 weeks). Thirty-one studies were of outpatients, one was located



in primary care, three were in inpatient populations and 13 in either mixed or unspecified settings. It was possible to determine baseline severity in 19 studies, with depression being classified in four studies as moderate, in six as severe and in nine as very severe. Meta-analysis indicated the possibility of publication bias.

NICE concluded that there is strong evidence that antidepressants have greater efficacy than placebo on achieving a 50% reduction in depression scores (“response”) in both severe and very severe depression. There was some evidence for a similar effect in moderate depression. The effect was similar in longer trials. However there was insufficient evidence to determine whether there was a clinically significant difference between SSRIs and placebo on increasing the likelihood of achieving remission. There was evidence to suggest that antidepressants were effective in the prevention of relapse in depression.

The guideline did not recommend the use of antidepressants in mild depression (four to six depressive symptoms according to ICD-10) “because the risk–benefit ratio is poor”.<sup>26</sup>

NICE concluded that all antidepressant drugs were of equivalent efficacy. The guidance noted that there was little evidence to support the dosing of tricyclic antidepressants above 100mg, nor the use of SSRI drugs above their “licensed dose”.

### **3.3.2.2 NICE guidance and clinical practice in relation to antidepressants**

There is evidence to suggest that patients with minor depression and adjustment disorder are frequently treated with antidepressant drugs, even though there is little or no evidence of pharmacological effectiveness for such conditions.<sup>112-114</sup>

A review of studies examining antidepressant prescribing found that almost all drugs in the SSRI class were prescribed at an effective dose, whereas only 15% of tricyclic prescriptions were prescribed at 125mg or more.<sup>115</sup> In a Scottish study of 20,195 patients taking antidepressants, 72% of tricyclic and 8% of SSRI prescribing was at a sub-therapeutic dose.<sup>116</sup>

Endorsing a prior review by Geddes,<sup>117</sup> NICE made a strong recommendation that drug treatment should be continued for at least six months after evidence of effectiveness. Many patients do not experience a full recovery when treated with antidepressant drugs alone: in clinical studies, about one-third of patients achieve a full remission, one-third experience a response and one-third are non-responders.<sup>119</sup> Partial response is therefore a common problem with drug treatment. Psychotherapy may have a role to play in improving outcomes for patients.<sup>120</sup>

### 3.3.2.3 Summary

Trials of antidepressant treatment are complicated by high rates of placebo response and natural remission. Research in this area is particularly affected by publication bias, and research trials may have limited applicability to “real world” settings.

Nonetheless, NICE guidance and other work could be summarised as follows:

- Antidepressant use for people with moderate to severe disorder was likely to be beneficial, though the effect size is small
- There was no evidence to suggest clinically significant benefit from antidepressants in mild depression, though one study in UK primary care has detected small but statistically significant treatment effects.<sup>121</sup>
- Outcomes were best for patients with no previous history of depression, with milder symptoms, and with a shorter duration of illness
- Full remission of symptoms may correlate with reduced longer-term risk of relapse
- Treatment trials with antidepressants need to be continued beyond six weeks to establish full benefit
- Switching and augmentation strategies may improve clinical outcomes
- Clinical interventions might benefit from attention to benefits conferred by the “placebo” components of treatment. This will relate to all aspects of participation in a trial apart from the active drug, and includes the motivation to participate, regular monitoring and follow-up, and a structured approach to care.

- Research subjects are clearly motivated to make choices about treatment, and compliance (and possibly outcomes) are better in those who could access their preferred forms of treatment.

### *3.3.3 Effectiveness of antidepressants in routine practice*

The following section outlines the evidence relating to the effectiveness of antidepressant drugs in the acute treatment of depression. This topic relates not only to the technical “efficacy” of antidepressants as measured in clinical trials, but to the more complex concept of “effectiveness” in routine practice.

Research seeking to establish the response to drug treatments for depression faces a number of methodological challenges. As discussed above, depression is difficult to define (section 3.2.1), and measuring outcomes in people with low mood may not always be straightforward (section 3.4.1). Given the complexities of clinical practice, randomised controlled trials may therefore overestimate the “real-world” effectiveness of antidepressants.<sup>122</sup> Statistically-significant changes in depression scores may not represent clinical significance for patients. NICE defined clinical significance in relation to the Hamilton Rating Scale for Depression<sup>123</sup> as a three-point difference in scores. Notwithstanding concerns that the scale itself may be “psychometrically and conceptually flawed”,<sup>124</sup> this represents a relatively small change (6%) in a scale that has a maximum score of 52 points.

Nonetheless, trials do report “significant” clinical effects of smaller size. For example, the Threshold for Antidepressant response study—while acknowledging the effect was small—concluded that “treatment with an SSRI plus supportive care is more

effective than supportive care alone for patients with mild to moderate depression”.

Yet the mean differences in HDRS scores between drug-treated and control groups were just 2.3 points at 12 weeks and 1.7 at 26 weeks.<sup>121</sup>

Two issues particularly complicate the assessment of trials of antidepressant efficacy: the placebo effect and publication bias.

### **3.3.3.1 The placebo effect**

The “placebo” effect in antidepressant trials is unusually large compared with that observed for other conditions.<sup>125</sup> In a review of 19 placebo-controlled trials of antidepressants, Kirsch and Sapirstein<sup>126</sup> found that three-quarters of the improvement shown in the drug-treatment groups was attributable to placebo. The influence of “placebo” arises due to the placebo effect proper (the sensitivity of patients to the non-drug therapeutic aspects of the trial), but is amplified by the natural history of depression. As discussed in section 3.2.2, there is a high spontaneous remission rate in the first three to six months of a depressive episode.

Kirsch and Sapirstein<sup>126</sup> estimated that improvements in the drug-treatment group could be attributed as follows: 25% to the active drug ingredient, 25% to natural improvement over time, and 50% to the placebo effect. Since most spontaneous remission occurred within 3 months, some authors suggest that studies should only include subjects who had been depressed for at least this period of time.<sup>127</sup>

Placebo-controlled antidepressant trials have shown that patients with a shorter duration of depressive illness (one to six months) failed to show benefits of drug treatment over placebo, whereas those with longer durations did.<sup>128</sup> Placebo effects above 40% may make smaller studies (under 300 patients per cell) underpowered.<sup>129</sup>

Patients given their preferred treatment in clinical trials are probably more likely to comply and to have better overall outcomes;<sup>130</sup> patients with a strong preference for psychotherapy are unlikely to join or comply with antidepressant trials, which may distort their findings.<sup>131</sup>

It should be noted that most depression rating scales such as the Hamilton Rating Scale for Depression<sup>123</sup> contain items—such as sleeping difficulties, anxiety, and agitation—that are not specific to depression, and which may respond to nonspecific sedative effects associated with many antidepressants.<sup>132</sup> Such a non-specific “antidepressant” action has been noted in trials of agents as diverse as methylphenidate, benzodiazepines, and antipsychotics.<sup>133</sup>

A review of 75 placebo-controlled trials for depression conducted between 1981 and 2000 found that the placebo effect was not only significant, but rising: the proportion of patients responding to placebo increased at the rate of approximately 7% per decade.<sup>134</sup> The reasons for such an increase are unknown, though may have been influenced by a trend towards conducting trials in patients with less severe depression because of ethical concerns regarding appropriate treatment for very ill or suicidal patients.<sup>135</sup> Early efficacy trials often use symptomatic volunteers, recruited through media advertising. Such subjects are not typical of self-declared patients seen in practice settings: they are less likely to have significant medical or psychiatric complications, or to have chronic depression.<sup>26</sup> Efficacy trials may therefore generalise poorly to actual practice.<sup>122,136</sup>

A meta-analysis of all the clinical trials submitted to the Federal Drug Administration for the licensing of fluoxetine, venlafaxine, nefazodone and paroxetine illustrates how these issues may interact in practice.<sup>137</sup> The study found that antidepressants were

effective only in the most severely depressed patients, and that this was mediated principally by a reduction in placebo effect for this group, rather than a specific increase in pharmacological effect.

Although clearly a complicating factor in the design of drug trials, the fact that many people recover without active treatment should not be considered a “negative”. In fact, the strength of the placebo effect should perhaps guide us towards emphasising other aspects of patient care.

“Perhaps we should actively strive to potentiate the placebo effect when treating people with depression. The prescription of drugs alone is not enough to get people fully better, whereas drugs, good clinical care, and elements of cognitive-behavioural therapy like structured problem-solving and pleasant event scheduling, may well be.”<sup>125</sup>

There may be potential, therefore, for services to improve outcomes for patients by optimising the factors that enhance the “placebo” and non-specific therapeutic components of treatment.

### **3.3.3.2 Publication bias**

There are indications that antidepressant trials are affected by substantial publication bias. A review of 74 antidepressant trials registered with the American Federal Drug Administration revealed that 31% of these were not published. The published record suggests that 94% of the trials conducted were positive. In fact, only 51% were positive when unpublished trials were taken into account.<sup>138</sup> It is not known whether this publication bias relates to a failure to submit or publish manuscripts with “negative” findings, but the potential to distort the research base is clear. Some have

advocated that licensing authorities should insist on publication of data from all registered trials.<sup>139</sup>

### *3.3.4 Influences on antidepressant prescribing*

Once a diagnosis of depression is made, most patients are given a prescription for an antidepressant. Eighty-one percent of all patients diagnosed with depression received at least one prescription for antidepressants in a large UK study of primary care prescribing.<sup>110</sup> Seventy-three percent of New Zealand primary care attenders<sup>140</sup> and 94% of Australian primary care patients<sup>141</sup> received an antidepressant when they had a diagnosis of depression. The proportion of American patients receiving a prescription for depression increased from 70% to 89% between 1987 and 2001.<sup>102</sup>

The greater the severity of symptoms, the more likely GPs are to “medicalise” low mood and treat with antidepressant medicines.<sup>140</sup>

Doctors' perceptions of patients' expectations strongly predict the decision to prescribe, yet doctors may be making inappropriate decisions “without checking whether their assumptions about patients' preferences are correct.”<sup>142</sup> In one study, 7% of prescriptions had not been wanted or expected by patients beforehand, and doctors recorded that one in five prescriptions they wrote were not strictly indicated.<sup>143</sup> Patient pressure does have an influence on prescribing, but doctors may overestimate “direct pressure” from patients, or even how sure they are about what patients want from the consultation.<sup>142,144</sup>



Patients and doctors have moderate differences in the priorities they attach to a choice of drug. Although doctors and patients agreed that common side effects were the most important factor, patients were more concerned about uncommon side effects than doctors, and doctors more concerned about cost than patients.<sup>145</sup> Not surprisingly, GP attitudes towards the effectiveness of drugs does influence their prescribing decisions.<sup>146</sup>

There is evidence to suggest substantial public resistance to the use of antidepressant drugs to treat low mood. Even after a 5-year campaign run by the Royal College of Psychiatrists and Royal College of General Practitioners to “defeat depression”, only 24% of the public thought that someone with depression should be offered antidepressants, and 74% thought that they were addictive.<sup>147</sup> A review of sixteen studies of preference for talking treatments or medicines in the treatment of depression found unanimously in favour of psychotherapies.<sup>131</sup>

Van Schaik and colleagues conclude from their review that when clinicians supported patients’ preferences, patients could be encouraged to use the treatment that was most suitable for them. In addition, it was found that patients who strongly preferred counselling but did not receive it were likely to go without treatment altogether.<sup>131</sup>

A service that can offer both psychotherapy and pharmacotherapy is therefore more likely to be able to attract people into treatment, and to encourage their concordance with that treatment. Careful attention to actual, rather than inferred, patient preferences could align clinician and patient perspectives and improve outcomes overall.

The influence of pharmaceutical marketing on prescribing decisions is difficult to measure directly, but evidence suggests that it is likely to be substantial,<sup>148</sup> and not always in the best interests of the patient or the health system.<sup>149,150</sup>

### *3.3.5 Concordance with treatment*

Far fewer people take antidepressants than are prescribed them, and rates of drop-out from treatment are high.<sup>151</sup> Non-compliance rises from about 30% within a month of treatment to 50-70% by 3 months of treatment.<sup>152,153</sup> Overall perhaps only about 50% of all prescriptions are taken as prescribed.<sup>153</sup>

Drop-out rates in primary care may be higher for tricyclic than SSRI drugs, though any effect is less marked in studies in secondary care settings.<sup>153,154</sup> A positive attitude towards medicines was the most important predictor of adherence in one study, which also found that experience of adverse effects, early treatment response, longer onset of depression, and a higher educational level predicted better concordance.<sup>155</sup>

Mismatch between treatments preferred and treatment actually received acts as a significant barrier to sustained adherence. Patient concerns about antidepressant side effects and general worry about taking antidepressants were independent predictors of antidepressant non-use.<sup>156</sup>

An American study evaluated the effect of a programme designed to improve concordance and outcomes for primary care patients who had experienced multiple episodes of depression. Provision of two additional primary care visits and three telephone calls by a depression specialist improved compliance with antidepressant

treatment from 58% to 72% at 3-6 months and 50% to 63% at 12 months follow-up.

The intervention group had significantly improved depression scores compared to the usual care group, but relapse rates were not different.<sup>157</sup>

Provision of psychotherapy and the selection of an appropriate antidepressant medication may reduce the risk of discontinuation during the first 3 months.<sup>158</sup> A systematic review of 16 studies comparing outcomes and adherence for people taking antidepressants alone or in combination with psychotherapy<sup>159</sup> found that combination treatment was associated with greater improvement. Longer psychotherapies were associated with a lower drop-out rate. It was not clear to what extent the improved outcomes related to a direct effect of psychotherapy, as opposed to a consequence of improved medicines compliance. Provision of combined psychotherapy and pharmacotherapy for depression provided lower cost care per quality-adjusted life year than both usual care and psychotherapy alone.<sup>160</sup>

However some authors assert that there “is an uncritical assumption that improved adherence is always a desirable goal, and that the clinical task is to overcome the barriers in its way”.<sup>161</sup> Qualitative work emphasises that the decision to stop taking psychotropic drugs is often not a form of “patient shortcoming” associated with forgetfulness or lack of insight, but instead a thoughtful, personal decision. Such decisions took into account the “attribution” of depression to a medical problem, and weighed up the benefits and disbenefits of medical treatment (especially adverse effects). “Stopping and seeing what happens” was a common strategy used by patients.<sup>161</sup>

Concerns about dependency and being reliant on a chemical played a key factor in people's assessment of their SSRIs. While individuals felt normal with medicines, they also perceived they would only be able to feel completely normal without them. The quest for normality and desire to manage their emotional state without the need for medication led respondents to want to quit their treatment.<sup>161</sup>

### *3.3.6 Measures of antidepressant prescribing*

Technical issues relating to the measurement of antidepressant use will be dealt with in some detail in this section, since this has a direct bearing on the reporting and interpretation of prescribing information in the Results section. The Defined Daily Dose (DDD) of a drug is a theoretical unit of measurement defined by the World Health Organisation as the "assumed average maintenance dose per day for a drug used for its main indication in adults."

The level at which the daily dose is "defined" is a reference unit that may not reflect the recommended or typical use of that drug in particular countries or clinical settings.

Table 3-1 compares these Defined Daily Doses for some commonly-prescribed antidepressants with the standard and maximum doses recommended by the British National Formulary.<sup>162</sup>

Drug	Defined Daily Dose <sup>163</sup>	Standard treatment dose <sup>162</sup>	DDD as % of maximum British National Formulary
fluoxetine	20mg	20mg	33% (60mg)
citalopram	20mg	20mg	33% (60mg)
venlafaxine	100mg	150mg	27% (375mg)
amitryptiline	75mg	75- 150mg	38% (200mg)
lofepramine	105mg	140- 210mg	67% (210mg)

**Table 3-1: Defined Daily Doses (DDD) and percentage of maximum British National Formulary doses for commonly-used antidepressants**

It can be seen that most Defined Daily Doses and formulary doses are equivalent (with the exception of lofepramine) but that Defined Daily Doses are typically only a fraction of the maximum British National Formulary dose, and in the cases of venlafaxine, lofepramine and amitryptiline are also lower than the standard recommended British National Formulary dose.

### **3.3.6.1 Interpreting doses and clinical use**

Routinely-collected prescribing information in Scotland only counts the amount of drug dispensed; it does not record the dose to be taken or the duration of treatment. This means, for example, that prescribing “three Defined Daily Doses of fluoxetine” could mean three people receiving a standard dose of 20mg, or one person receiving the maximum British National Formulary dose of 60mg.

Scottish data does not yet allow for a comprehensive linkage to be made between drug use and the condition for which it was prescribed. For example, it is not possible to know what proportion of amitryptiline use relates to depression and what proportion is prescribed for other indications (such as enuresis or neuropathic pain).

### 3.3.6.2 Artefact and national recording of Defined Daily Doses

Information about antidepressants is collected by the Information Services Division of the Scottish Government, and is based not on prescriptions written, but on drugs dispensed. Defined Daily Doses vary by about 10% between months, following a consistent pattern from year to year. This variation is mainly caused by the different number of days in each calendar month, but is also influenced by increased GP prescribing before the Christmas and Easter public holidays. Analysis of prescribing trends therefore needs to be averaged over a period of months, or to use comparisons for the same periods each year in order to take account of artefactual variation.

The Scottish population is not static, so the calculation of Defined Daily Doses dispensed per head of population needs to be adjusted for any changes in the denominator. In practice, this can only be done once per year, when the General Register Office of Scotland publishes the national population estimate.

For these reasons, analysis of prescribing in this study:

- Used World Health Organisation definitions of Defined Daily Doses, since other more accurate measures are not routinely available in Scotland
- Makes year-to-year comparisons against equivalent time periods

Calculates antidepressant use at practice level using monthly practice populations and at national level using annual population estimates (the most detailed data available in both instances).

### 3.4 Psychological therapies

#### 3.4.1 *What types of therapy are effective for depression?*

A range of different psychological models have been applied to mental health problems, and different ‘schools’ or modalities of therapy have grown up around them. A review of brief psychological therapies for depression found trials investigating 32 distinct psychological models or techniques.<sup>164</sup> A detailed discussion of the rationale, effectiveness and availability of the full range of talking treatments is beyond the scope of this thesis. The purpose of the following section is to set out briefly the current clinical consensus.

The term ‘Psychological Therapies’ as used in this section is consistent with the following definition:

“A range of interventions, based on psychological concepts and theory, which are designed to help people understand and make changes to their thinking, behaviour and relationships in order to relieve distress and to improve functioning. The skills and competencies required to deliver these interventions effectively are acquired through training, and maintained through clinical supervision and practice.”<sup>30</sup>

Several forms of psychological therapy are available and recommended by the National Institute for Clinical Excellence for use in depression care.<sup>26</sup> Generally speaking, psychological treatments (including guided self-help) are considered the treatments of choice in mild depression; are an alternative to antidepressant use in moderate depression; and cognitive therapy with antidepressant drugs is the

treatment of choice in severe depressive episodes. Cognitive therapy is also established as a treatment to reduce the risk of relapse of depression.<sup>165</sup>

A critique from a psychoanalytic psychotherapy perspective argues that the studies upon which such reviews are based are fundamentally flawed. Perhaps most importantly, “patients complain of problems of functioning and of life not captured by measures of symptoms or categorical diagnoses”, and that “apparently exact rates of diagnosis lend pseudo-objectivity to the familiar taxonomy”, meaning that anxiety, depression and obsessive-compulsive symptoms are considered as separate disorders- a “dismemberment” of related difficulties that analysts consider unjustified and inappropriate.<sup>51</sup>

The validity of clinical trials comparing one form of psychotherapy against another has also been called into question, since the common features described above mean that the therapies may not represent “distinct treatments”.<sup>166</sup>

While acknowledging these critiques, the Doing Well programme was based on a conventional reading of the literature in this area.

There is no evidence to suggest that there is a “specific” form of psychological treatment for depression.<sup>167</sup> In fact, while therapies may begin from very different theoretical standpoints, independent coding of the content of therapies suggests that there is considerable overlap in their functioning in practice.<sup>166</sup> Effective therapies for depression typically have the following characteristics:<sup>165</sup>

- The therapy offers a specific formulation of the individual’s problems
- The model of therapy is shared openly with the patient



- There is rational use of techniques in a logical sequence
- There is an emphasis on skill development and transfer of learning to the patient outside of therapy sessions
- Change is attributed to the patient's rather than the therapist's efforts

In all psychological interventions, an appropriate therapeutic alliance is associated with a positive outcome, regardless of the modality of therapy offered.<sup>26</sup> This refers to the patient's capacity to work productively with the therapist because the therapist is perceived to be a "helping professional with good intentions". The nature of the therapeutic alliance in the opening sessions of therapy may be predictive of the eventual outcome.<sup>168</sup> Despite the importance of the therapist-patient interaction, a systematic review did not consider that any of the 83 available measures of this interaction were of sufficient quality to guide practice.<sup>169</sup>

In summary, most therapeutic models show considerable overlap, the principal common factors can be identified, and our current knowledge does not permit us to assess reliably patient-therapist interaction.

There are three contemporary UK reviews of the evidence in relation to psychological treatments for depression: the National Clinical Practice Guideline for depression prepared by the National Institute for Clinical Excellence,<sup>26</sup> the Scottish Intercollegiate Guideline Network Guideline on Non-Pharmacological Management of Depression in Adults<sup>170</sup> and the Scottish Government's "Guide to delivering evidence-based Psychological Therapies in Scotland: the Matrix".<sup>30</sup> The NICE and SIGN guidelines are based on systematic reviews of the evidence; the "Matrix" report is a "summary of information" about psychological therapies intended to support NHS Boards to

commission appropriate services. It is included here because it represents official policy on the commissioning of psychological therapies in Scotland (though it was not available at the time when the Doing Well intervention was set up).

Table 3-2 sets out the recommendations made by these bodies for depression care.

Therapy	Description, rationale	NICE graded evidence of efficacy <sup>26</sup>	SIGN-graded evidence of efficacy <sup>170</sup>	"Matrix" evidence of efficacy <sup>30</sup>	Notes
Cognitive-behavioural therapy (CBT)	a structured, problem-focused, goal-orientated approach based on a model that changing cognitive biases in depressive thinking mediates changes in mood and behaviour	B; A when used with antidepressant in chronic depression	A	A	Good evidence of effectiveness for individuals with mild to moderate depression and in combination with antidepressants for severe and resistant depression. Good evidence lacking in treatment of severe depression without concomitant antidepressant use. "Treatment of choice" in moderate, severe & treatment-resistant depression <sup>26</sup>
Interpersonal therapy	Intended as a short-term treatment for depression, targeting areas of interpersonal functioning, eg role transitions, disputes, unresolved grief, isolation and withdrawal	B	A	A	Superior to placebo and equivalent to antidepressant drugs for individual therapy in mild/moderate depression; not as effective as antidepressant drugs in severe depression.
Psychodynamic therapy	a relatively intensive therapeutic approach aimed at reducing inner tensions and relational conflicts through the exploration of unconscious meanings and motivations, often with reference to past formative experiences and current care relationships	n/a	B	n/a	Uncertain evidence of efficacy in one trial for moderate depression. "Psychodynamic psychotherapy may be of value in the treatment of the complex comorbidities that may be present along with depression" <sup>26</sup>
Behavioural activation	A re-engagement in meaningful and necessary activities, without considering possible cognitive distortions	n/a	A	A	"No evidence" with which to compare efficacy with other forms of psychotherapy. <sup>26</sup> Effects may be similar to cognitive therapy and medication, though needs to take place in a "skilled therapeutic context".

Family and couple interventions		B	n/a	n/a	“Insufficient evidence on which to base a recommendation” <sup>170</sup> ; “consider for people who have a regular partner and who have not benefitted from brief individual intervention” <sup>26</sup>
Problem-solving therapy	shifts the focus of therapy from the client to the framework of the family unit, emphasising the social context of problems	B (mild depression)	B	n/a	“may be considered a treatment option”; <sup>170</sup> may be no more effective than usual care. <sup>171</sup>
Counselling	typically brief interventions that offers empathic and non-directive support for challenging circumstances	B (mild depression)	B	n/a	“may be considered as a treatment option” but effects inconsistent and probably no additional benefit after 12 months
Self-help guided by therapist	A self-administered intervention designed to treat depression, which makes use of a range of books or a self-help manual that is based on an evidence-based intervention and is designed specifically for the purpose.	C (mild depression)	A (mild to moderate depression)	A	

**Table 3-2: types of psychological intervention available in Scotland and evidence for their efficacy for depression in adults. Grading of evidence generally from A (strongest) to C (weaker). Details in Appendix 10.1, page 280**

There are clearly some differences in the conclusions drawn from these reviews of evidence.

It is beyond the scope of this chapter to investigate or explain all these differences.

Nonetheless, it is relevant to acknowledge that:

1. This is an active field for research, with a rapidly expanding evidence base.<sup>172</sup>

Decisions about what to include in the Doing Well intervention were made prior to the publication of NICE guidance in 2004, but were based on the same evidence and were consistent with that guidance. A significant number of new studies have added to the body of knowledge since NICE guidance on the management of depression was first published.

2. “Objective” appraisal of the evidence will nonetheless depend on some subjective judgements on the behalf of the reviewer, and there are some subtle differences in the standards used to grade evidence.
3. The implementation of psychological therapies at a service level will be influenced by policy and resources as well as the available “evidence base”.
4. There may be doubts about the “fidelity” to theoretical models when care is delivered in practice.

### *3.4.2 Issues in the delivery of psychological therapies*

#### **3.4.2.1 Which patient?**

The selection of a particular therapeutic modality for a patient will depend not only on the availability of that therapy, but on the patient’s own preferences and experience, on the

GP's awareness of the available options and the access to other services that may also be available.

A Healthcare Commission survey of over 18,000 people in secondary care mental health services in England in 2006 found that 39% of patients received "talking therapy", though 57% would have liked such treatment. However only 52% of those who did access "talking therapy" found it helpful.<sup>173</sup>

It would clearly be beneficial to be able to predict and select which patients might benefit from psychological approaches to managing depression. A systematic review of the clinical effectiveness of psychological treatments<sup>174</sup> found that outcomes were not greatly affected by the gender or age of patients. There was some evidence to suggest that patients from ethnic minority backgrounds had better outcomes in short-term psychodynamic therapy when their ethnicity was matched to that of the therapist. Other reviews did not find any association between ethnicity and outcome. Three studies found no evidence of an effect of intelligence on outcome. One study suggests that low socioeconomic and educational status is associated with poorer outcomes, but three studies suggested no effect. Not surprisingly, people who have difficulties in interpersonal relationships tend to have poorer outcomes in therapy.

#### **3.4.2.2 Mode of treatment**

Group and individual therapy were generally found to be of equivalent efficacy, except for brief therapies, which generally had better outcomes in individual rather than group work.<sup>174</sup>

#### **3.4.2.3 Duration of treatment**

A range of short-term psychological therapies have been developed that are based on the principles of counselling, problem-solving therapy, psychodynamic psychotherapy and

cognitive behavioural therapy, but which cover the same material much more quickly. Such “brief” therapies typically take place over six to eight sessions (although “brief” psychodynamic psychotherapy usually means up to 20 sessions,<sup>51,168</sup> some have advocated that interventions can be as brief as ten minutes<sup>175</sup>). They require patients to be able to understand the rationale of therapy, to articulate their difficulties, to quickly form a therapeutic alliance with the therapist, and to be able and motivated to work on problems outside the therapy session. Patient and therapist need to be able to identify the focus of treatment in the first one or two sessions.<sup>168</sup>

Two systematic reviews suggest that brief therapies are more effective and more acceptable to patients than either placebo or wait list control. Short-term therapies seem to work at least as well as GP care and antidepressant treatment, but the evidence in relation to short-versus longer-term therapy is less clear cut.<sup>26,164</sup> In general, treatments based on cognitive behavioural therapy had similar outcomes to those achieved by interpersonal therapy, and better outcomes than psychodynamic or supportive therapies.<sup>164</sup> Psychoanalytic psychotherapy is much longer than any other form of psychological treatment (often 45-300 sessions).<sup>51</sup>

No effect of treatment length on outcomes for therapy in depression was found in two studies, but there was some evidence that 16 weeks of CBT or IPT may be insufficient for people recovering from major depressive disorder.<sup>174</sup>

A “stepped care” model providing psychological therapies should be able to broadly match the appropriate duration of therapy to patient needs. This will partly be determined by the formulation generated after assessment. For example, a patient who experienced prolonged childhood adversity and who describes longstanding mood problems is unlikely to gain adequate benefit from a brief intervention: they would best be referred directly for longer-

term treatment. Other cases are less clear-cut, and the appropriate duration best established by monitoring their response to treatment. Those showing adequate benefit from a few sessions of therapy could safely be discharged; those showing a partial or absent response would require longer-term intervention.

#### **3.4.2.4 Access**

The National Institute for Health and Clinical Excellence (NICE) has recommended that a range of psychological therapies be made available on the NHS.<sup>26</sup> Only one quarter of the estimated 6 million people in England with anxiety and depression receive psychological treatment, which led to the development of the “Improving Access to Psychological Therapies” (IAPT) programme. The objective of the programme is to support Primary Care Trusts in England to implement NICE guidance.<sup>176</sup>

A similar commitment (to “increase the availability of evidence-based psychological therapies for all age-groups in a range of settings and through a range of providers”) was made in the Scottish Mental Health Delivery Plan.<sup>37</sup>

There is considerable unmet need for treatment with psychological therapies in both primary and secondary healthcare in the UK.<sup>81</sup> The difficulty in accessing appropriate psychological therapies was cogently expressed by Layard<sup>7</sup>:

“If you have schizophrenia or bipolar depression in Britain, you will generally get specialist help from the NHS. But only about 1% of the British population have these terrible conditions. Many more (some 15% of us) have unipolar depression or anxiety disorders, yet if you have one of these, often crippling, conditions you are unlikely to get any specialist help at all. You can see your general practitioner, but he or she is unlikely to prescribe any treatment other than drugs.”



This position is supported by surveys of GPs. A nationally representative sample of 200 GPs in England were asked their views about forms of depression care in self-completed online questionnaire.<sup>177</sup> Fifty-five percent of respondents believed that some form of psychotherapy or counselling was the most effective response to mild or moderate depression (35% believed that antidepressants were the most effective response for this group). Seventy-eight percent of doctors reported that they had prescribed an antidepressant while believing an alternative would have been preferable. The commonest reasons for prescribing were either that a suitable alternative was not available (66%), or involved too long a wait (62%).

Layard<sup>7</sup> estimates that 10,000 additional therapists will be required to meet the need for therapies, but others predict that the cost may be even higher.<sup>178</sup> It is relevant to note that the £338,546,700 spent on antidepressants in England in 2005 was more than double the “planned spending on psychological therapies” (excluding primary care) of £142,047,000 for the same year.<sup>179</sup> However Priebe<sup>101</sup> cautions that increasing psychotherapy provision in the UK “will absorb large amounts of funding and that the demand will not stop increasing once a certain level of provision has been reached.”

A number of issues are thought to have impeded the development of appropriate psychological therapies in Britain.<sup>81</sup> These include a perceived lack of efficacy of psychological therapies (despite the evidence referenced above), the relative cost of psychological therapies and “few distinct models of service delivery”. The report also identified a lack of suitably trained staff, limited access to appropriate training, and difficulty in using specialist skills in everyday practice. The view of the Royal Colleges was that poor integration between secondary and primary care was also thought to hinder access for patients.

In summary, services seeking to address these problems might provide brief interventions to manage cost and resource restraints. Longer or more intensive treatments would be reserved for those with clear indications for such approaches, or who had failed to show an adequate response to less intensive treatments. Psychological approaches should be based on validated models, with a particular focus on the “common factors”. A significant investment would require to be made in staff training and supervision. Finally, care should be taken to enhance integration between primary and secondary care.

### 3.5 Self-help for depression

The term “self-help” is used here to refer to a range of interventions (including interactive internet or paper-based packages), which patients may work through alone:

“the patient receives a standardised treatment method with which he can help himself without major help from the therapist. It is necessary that treatment be described in sufficient detail, so that the patient can work through it independently. Books, in which only information about depression is given to patients and their families, cannot be used”.<sup>180</sup>

“Guided self-help” refers to the use of these materials with limited support from a health care professional (or para-professional) who typically introduces the self-help programme and reviews progress and outcome. Such an intervention usually takes place over 6 to 8 weeks”<sup>26</sup>

The use of self-administered treatment manuals has been available since the 1960’s.<sup>181</sup> Originally developed as a technique for personal “self-improvement”, self-help now has an established place in the treatment of illness. This development has been viewed with scepticism by some authors: is it a “philosophical approach” that supports individual responsibility and self-efficacy, or a resource-driven “health technology solution to volume and demand”, improving nominal access to psychological therapies by providing a cut-down version of what professionals do?<sup>182</sup> It may, of course, be both: and even a “cut-down” version of therapy may be preferable to nothing at all.

Self-help has several potential advantages over conventional face-to-face psychotherapy. It is more accessible, less constrained by capacity issues, is private and has been argued to be

an “empowering” tool that may help to prevent the deterioration of depressive symptoms.<sup>181</sup>

As described in section 3.4.1, several systematic reviews have supported the effectiveness of self-help techniques in depression. Guided self-help has been recommended both by NICE<sup>26</sup> and the Scottish Intercollegiate Guidelines Network<sup>183</sup> for patients with mild (NICE) or mild to moderate (SIGN) depression. Computerised self-help is also supported by research evidence.<sup>183</sup>

However NICE recommendations are based on only nine randomised controlled trials including 453 participants. SIGN guidance was itself based on NICE, with the addition of a more recent meta-analysis involving 34 studies.<sup>184</sup> This latter report noted some significant methodological limitations in the studies examined, and suggested that outcomes may be less positive in symptomatic primary care patients or waiting list controls, rather than volunteer subjects recruited through advert.<sup>185</sup> Outcomes were better for “guided” rather than self-directed self-help, for people with established symptoms rather than those at risk of depression, and for interventions based on cognitive behavioural therapy techniques.

There are no direct comparisons of the self-help materials available, and a meta-analysis of 11 studies assessing three self-help books found evidence of effectiveness in only one (a US resource called “Feeling Good”).<sup>186</sup>

Guided self-help has been proposed as “step one” in a stepped care system in the UK, and seems to be capable of increasing the number of people supported in primary care with no loss of effectiveness compared to traditional services.<sup>187</sup> In this sense self-help is considered an adjunct to “conventional” health services, particularly used in mild problems and in health promotion.

Advocates of self-help envisage a more ambitious or radical “consumerist” model, which represents a confident vision of patient-focussed care, rather than being relegated to the margins of the system. This alternative vision would enable patients to access care directly in a “graduated, non-linear way titrated to their needs”. Reform of this kind, it is argued, would empower patients to find the right help while avoiding the delay and bureaucracy associated with conventional referrals, consultations and discharges: “a knowledgeable, informed public may be better able to improve its own health and manage its progress through the whole system without necessarily overwhelming the system.”<sup>188</sup>

Papworth<sup>181</sup> suggests that individuals should be offered an intervention based on their presenting difficulties, personal preferences and their individual characteristics, perhaps within a flexible stepped care model.<sup>189</sup> Such an approach might extend to population-based initiatives seeking to reach people who might never otherwise come into contact with health services.<sup>182</sup> There is some limited evidence to support the effectiveness of self-management programmes by lay leaders for people with depression.<sup>190</sup>

“The response of primary care professionals to patients with common, minor illnesses is itself a determinant of subsequent patterns of healthcare seeking behaviour. More research is needed to guide practitioners towards the optimum ways of configuring services, interacting with patients, and providing drug and non-drug solutions to illness.”<sup>191</sup>

Self-help is not, however, suitable for all patients. Subjects with high levels of “self-efficacy” and “realistic” personality traits may do better than others when using such materials,<sup>181</sup> whereas those with poor functional literacy are unlikely to benefit. Self-help is considered unsuitable for people with suicidal thoughts or impaired attention and motivation, even though these are difficulties commonly associated with depression.<sup>192</sup> A small proportion of

patients may experience harm when using self-help without professional support.<sup>181</sup> Some authors have questioned GP's readiness to provide such support for patients seeking self-help for depression in primary care.<sup>193</sup>

In summary, a self-help approach may exclude some people who find the materials too hard to read or absorb; may have significant drop-out rates; and difficulties experienced while using the material may exacerbate feelings of hopelessness. Nonetheless, the benefits of self-help (ease of delivery, low cost, reduced referrals to specialist services, acceptability to patients) offer clear potential for those who can engage. A move towards strategies to improve patient information, participation and engagement in treatment would be consistent with similar trends in general health care settings.<sup>82</sup>

### **3.5.1.1 Self help in practice**

About 2,000 self-help books are thought to be published each year,<sup>26</sup> and a large number of these relate to depression. However in 2003, when the Doing Well intervention was being planned, there was limited information available to guide the choice of self-help materials.

Nonetheless the local health system had participated for some years in the SPIRIT (Structured Psychosocial Interventions In Teams) course, which trained practitioners to work effectively at a basic level of cognitive behavioural therapy delivery. These skills included being able to formulate a management plan using a cognitive behavioural model to identify areas for change, to help the patient to identify and overcome unhelpful thinking and behaviours, and use the self-help materials based on the "Five Areas" approach and associated "Overcoming Depression" text<sup>194</sup> effectively and safely.<sup>195</sup> Since these self-help materials were available without charge, considerable local expertise had built up in their

use, and no comparative evaluations had been published at that time, a pragmatic decision was taken in 2003 to use the “Five Areas” approach as part of the Doing Well intervention.

### 3.6 Depression: management in practice

#### 3.6.1 *Detection in primary care*

Doctors stand “at the gateway between illness and non-illness”:<sup>196</sup> the GP must interpret a patient’s description of distress, and seek to make sense of their problems in the social, physiological and personal context in which the patient finds themselves. The traditional “rule of halves” suggests that “approximately half of most common chronic disorders are undetected, that half of those detected are not treated, and that half of those treated are not controlled.”<sup>197</sup>

Unlike other common conditions presenting to primary care, a diagnosis of low mood cannot be established with physical tests, and the distinction between “illness” and “non-illness” can be particularly hard to distinguish.

Studies commonly assert that that “up to half”,<sup>198</sup> “at least half”<sup>199</sup> or “about half”<sup>200</sup> of cases of depression amongst primary care attenders are not detected by general practitioners. A consensus statement by the “Defeat Depression” campaign stated that “at any consultation about half the patients consulting with depression are not recognised”.<sup>201</sup> These authors either cite studies from the 1970s reported by Goldberg & Huxley,<sup>78</sup> or more recent work by Simon<sup>202</sup> (where GPs actually identified about 64% of major depression).

But these figures may underestimate the true detection rate in practice. Studies examining this issue typically use dichotomous categories for “depressed” and “not depressed”.<sup>203</sup>

More recent work has shown that GPs respond in a more “dimensional” way in practice. A study in of 18,414 primary care consultations in Hampshire, UK,<sup>204</sup> showed that there was a close association between the severity of presenting depressive symptoms and the likelihood of illness being detected by GPs. The proportion of missed cases reduced



markedly when the threshold for a diagnosis was raised. Fifty-nine percent cases scoring 8 on the depression subscale of the Hospital Anxiety and Depression Scale were “missed” by GPs, but this proportion fell to 20% for people with a score of 17. The authors estimated that only one probable new case of depression would be missed in every 29 consultations.

An observational study in a Scottish primary care setting reported rates of depression diagnosis for three levels of score on the Hospital Anxiety and Depression Scale. Eight percent of patients with a score below eight were diagnosed as depressed, rising to 24% of patients with a score between eight and ten, and 52% of patients with a score above ten.<sup>205</sup>

An American study in primary care had similar findings: subjects reaching a “caseness” threshold for major depression were nearly three times more likely (56%) to be recognised than “sub-threshold” cases (20%).<sup>206</sup>

“Cross-sectional” studies may also give misleadingly low detection rates in primary care when they assess the proportion of cases “missed” at a single appointment. Studies with a longitudinal design suggest that unidentified cases are often picked up at subsequent visits, with one study suggesting that the rate of non-detection is “closer to one in seven than one in two”.<sup>207</sup>

Nonetheless, it seems likely that a significant proportion of presentations of depression are not picked up by GPs. A number of factors will influence detection rates. Doctors are less likely to detect new cases of depression when they face significant time pressures,<sup>208</sup> have knowledge and skill deficits<sup>198</sup> or have a consultation style that is less likely to enquire about “feelings and affect”.<sup>209</sup> Increasing consultation length was associated with better recognition of psychological distress in a Scottish study of 1,075 consultations: a 50% increase in consultation length was associated with a 32% increase in identification.<sup>210</sup>

Doctors' confidence in their own ability to identify depression was not associated with detection rates in a British study in primary care. However a "sense of ease" in managing depression and a belief in the possibility of successful treatment within primary care were both associated with increased detection rates.<sup>146</sup>

Patients are less likely to have their emotional needs recognised if they present with physical rather than psychological complaints,<sup>211-213</sup> have cultural beliefs about depression that prevent them from seeking help<sup>214,215</sup> or make them reluctant to take antidepressants.<sup>216</sup> Determining an appropriate threshold for diagnosis may be problematic where patients are experiencing stressful life experiences, a problem that is particularly common in deprived practice populations.<sup>217</sup>

The American Preventive Services Taskforce<sup>218</sup> recommended screening for depression in primary care, and the UK National Institute for Clinical Excellence recommended screening for at-risk patients.<sup>26</sup> But the instruments in use have low positive predictive value in primary care,<sup>219</sup> and a recent meta-analysis showed that the introduction of screening instruments for depression had no effect on the detection or management of depression (in non-specialist settings without adding other enhancements in care).<sup>220</sup> However it is possible that GP detection of symptomatic cases of depression may be improved by the use of objective scoring measures.<sup>199</sup>

There is little evidence to support a view that improved detection of depression improves clinical outcomes,<sup>206,221</sup> which may be in part because GPs and patients often choose not to treat cases identified in this way.<sup>222,223</sup> The conventional biomedical view that stresses the importance of managing symptoms may not be shared by patients, who are also concerned with issues of control and social functioning when they decide to seek help and assess their own progress.<sup>224</sup> Even where doctor and patient agree on the need for treatment,

concordance will vary, therapies may be ineffective – and many patients would have recovered without intervention anyway.

### **3.6.1.1 Clinician education**

The Doing Well programme was predicated on an assumption that there was scope to improve the management of depression in primary and secondary care, and that clinical behaviour in these settings was amenable to change. Yet optimism about the potential of educational initiatives to change clinical behaviour is often misplaced. (Section 3.7 reviews the literature on quality improvement in healthcare more generally).

In 1983 and 1984, the Swedish Committee for the Prevention and Treatment of Depression (PTD) organised a training programme on the diagnosis and treatment of depression to all the general practitioners on the island of Gotland in Sweden (population 58,000). In the following years, the suicide rate fell by 60%, and there were significant reductions in inpatient care and the frequency of sick leave for depression and rates of antidepressant use increased.<sup>225,226</sup>

The Gotland experience generated significant optimism that GP education could have a significant impact on the management and outcome of depression. Unfortunately this early optimism has not been supported by subsequent findings, in Gotland or elsewhere.

The maximum benefit in Gotland was seen in 1986, and by 1988 the effect had begun to fade, with suicide only slightly lower than baseline values. The study had significant limitations (for example, the small population size, significant cultural change over the period of the intervention, and a lack of effect on male suicides).

A review of 50 years of “education” of primary care physicians found equivocal evidence of efficacy.<sup>227</sup> Some studies seemed to increase knowledge and skill (as tested by multiple choice tests, video reviews and objective structured clinical examinations). However, other studies showed no effect on these parameters. Evaluation of a German intervention to implement depression guidelines in 29 primary care practices showed no change in patient outcomes.<sup>228</sup>

British studies suggest that training for GPs does not improve depression outcomes for patients,<sup>229-231</sup> though it may improve their confidence, communication skills and patient satisfaction.<sup>232</sup> Providing information leaflets about depression to primary care patients in the waiting room made no difference to the care they subsequently received.<sup>233</sup>

Even where GPs are aware of appropriate depression management strategies, they do not always practise in accordance with that knowledge. For example, although two thirds of GPs were aware of the “Defeat Depression” campaign, only 40% said that they had made changes in their practice as a result.<sup>234</sup> This applies both to delivery of care by GPs<sup>221</sup> and by other members of the practice team.<sup>235</sup>

Scepticism was expressed in the past about the authority of those doing the “educating” about depression,<sup>203</sup> and the validity of the guidelines themselves,<sup>236</sup> but the clinical consensus generally supporting subsequent NICE guidance went some way to resolving these issues.

In summary, GP behaviour in response to a patient presenting with depression often differs from what is considered to be “best practice”, even when they seem to be aware of the guidance and accept that it should influence their clinical care. This is a complex area, but it

seems likely that understanding clinical behaviour in real-life settings requires an approach that extends beyond knowing the “facts”.

The consultation is a two-way process between patient and doctor, and patient views about the appropriate response to depressive symptoms may differ significantly from those of their GP. A qualitative study of patient views about depression care in the north of England found that patients hold varied and complex views about the aetiology of their depression.<sup>237</sup> Causative factors identified by patients included biochemical causes, hereditary influences, personality traits, multiple demands and social problems. The attribution of their difficulties to life events was a prominent feature. There was a resistance to “disease management” strategies,<sup>238</sup> with many people considering such “medical” approaches as only one therapeutic option amongst many.

GPs share many of these views,<sup>9</sup> and may place a high value on “tacit knowledge” based on their personal qualities and experience. These factors may be considered more important than formal education when interacting with depressed patients,<sup>239</sup> not least because the distribution of educational materials generally has little effect.<sup>240</sup> Difficulty integrating a medical understanding of depression with a recognition of the social context of depression may lead to “dissonant descriptions of depression” from doctors.<sup>241</sup>

Taking these complexities into account, interventions to change GP behaviour might be expected to benefit from an individualised, tailored approach.<sup>242</sup> However a more recent review of 15 studies to tailor interventions to change behaviour in health care professionals showed mixed results. It therefore remains unclear whether “tailored” or “untailored” strategies show any benefit over each other- or no strategy at all.<sup>243</sup>

Reviews of methods for changing professional practice concluded that most interventions work to some degree, and that the use of multiple approaches in parallel was perhaps most effective.<sup>244,245</sup> There are few studies of different interventions compared against each other, and no controlled studies that have evaluated system-wide approaches to organisational development.<sup>240</sup>

However, the following interventions have been shown to have had some effect.

“Educational outreach visits” (also known as “academic detailing”) have a range of effects, from “non-significant to substantial”.<sup>246</sup> Outcomes are generally better where a small, specific change is targeted, e.g. in relation to prescribing, and where visits were combined with other interventions,<sup>247</sup> such as direct mailings to patients, patient counselling delivered by others, or clinical information collected directly from patients and given to the provider.<sup>246,247</sup> Expert opinion leaders are thought to influence through their authority and status; peer opinion leaders influence by virtue of representativeness and credibility.<sup>248</sup>

“Social marketing” approaches assess the motivation for current practice and barriers to change; educational interventions are then designed to respond to those needs. Some social marketing programmes target physicians and their “opinion leaders”, emphasising physician participation, the use of concise educational materials, the repetition of key messages and reinforcement through subsequent visits.<sup>247</sup>

This approach is very close to the marketing strategies of pharmaceutical companies, who have proved to be effective in influencing clinical behaviour (even though doctors tend to underestimate the influence of pharmaceutical marketing strategies).<sup>249</sup> This knowledge influenced the “marketing” strategy for *Doing Well*, which sought to bring about change in GPs by peer influence, group educational sessions, and the repetition of simple messages

with a consistent “brand”. This included the use of branded pens and mugs, as described in section 4.7.

### 3.6.2 *Clinical outcome measures*

The implementation of a stepped care model requires the continuous assessment and feedback of response to treatment, so as to be able to influence the type and intensity of care that is provided. Doing Well required to choose an appropriate measure before this became a requirement of the Quality and Outcomes Framework (QOF) in primary care in 2006,<sup>38</sup> or the Integrated Care Pathway for Depression in 2007.<sup>250</sup>

Recent work has found that both patients and GPs support the use of depression scoring tools, considering them to be a useful component of holistic care. Despite some initial scepticism, doctors were sometimes surprised by the score results, and did use this to change their behaviour.<sup>251</sup> Research also confirms that itemised symptom measures are more effective than “global judgment” in detecting modest change in symptoms that might otherwise not be reported.<sup>136</sup>

A depression measure was sought that would:

- Accurately assess depression severity at referral, so as to guide the type of clinician who would be allocated to a new case
- Be suitable for monitoring change during the course of treatment
- Allow for self-completion by the patient
- Be simple to understand and quick to complete

- Be cheap or free to use

There is a wide range of depression scoring measures, including several in common use, but a review of all these instruments falls without the scope of this chapter. Four established depression measures were considered, but two failed to meet the requirements set out above.

The accepted “gold standard” rating scale in clinical trials of antidepressants is the Hamilton Depression Rating Scale (HDRS).<sup>123</sup> Although used to assess outcomes since the late 1960s, the scale has been criticised for poor content validity and inter-rater and test-retest reliability.<sup>124</sup> Since the measure is not suitable for self-completion by patients, it was not considered further. The Beck Depression Inventory (BDI),<sup>252</sup> is a well-established scale and suitable for self-completion, but it was too costly for widespread use in this intervention.

Two further rating scales were considered: the Hospital Anxiety and Depression Scale (HADS),<sup>66</sup> and the Patient Health Questionnaire (PHQ)<sup>253</sup>. Their characteristics are discussed below.

### **3.6.2.1 Hospital and Anxiety Depression Scale**

The HADS was introduced in 1983 to support the identification of depression and anxiety in hospital-based medical outpatient clinics,<sup>66</sup> although it has subsequently been validated for use in primary care and community settings. An important consideration in the development of the scale was the avoidance of a large proportion of items relating to “somatic disorder”. Accordingly, five out of the seven items relating to low mood enquire about “pleasure response”. The scale deliberately excludes such “obvious implications of psychiatric disorder as suicidal inclinations” in case this might lead to suppression of self-report by the patient.<sup>254</sup>



The HADS takes two to five minutes to complete 14 questions such as “Do you take as much interest in things as you used to? Do you laugh as readily? Do you feel cheerful? Do you feel optimistic about the future?” Respondents are requested to give their answers in relation to the preceding week. Each item can be scored 0-3. Scores greater than 8 on either subscale suggest the possible presence of anxiety or depression, with scores above 11 suggesting “caseness” for these conditions.<sup>254</sup> The scale is available from a commercial publisher at a cost of 5-50p per item, but a block license was purchased by NHS Greater Glasgow and Clyde, so the scale could have been used by Doing Well without cost.

A review of 747 papers that used HADs supported the two-factor structure of the measure, which has strong correlations between the depression and anxiety subscales.<sup>254</sup> The HADs was found to be internally consistent, to have a good balance between sensitivity and specificity at a threshold of 8+ for both subscales (range between 0.70 and 0.90). In general practice populations, the areas under the curve were found to be 0.84 to 0.96, indicating very good case-finding abilities.<sup>255</sup>

### **3.6.2.2 The Personal Health Questionnaire**

The clinician-administered Primary Care Evaluation of Mental Disorders (PRIME-MD) was developed as a screening instrument for depression, but was found to take too long to administer. A nine-item shorter form suitable for self-completion was evaluated in primary care and found to have equivalent diagnostic validity to the PRIME-MD, but to be easier to use. This measure became known as the Patient Health Questionnaire (PHQ, or PHQ-9).<sup>256</sup> Although the measure does not assess anxiety symptoms, it is compatible with a 7-item scale called the “GAD-7” used to assess generalised anxiety disorder.<sup>257</sup>

The 9 questions are rated from one to three, based on the frequency of symptoms experienced in the previous two weeks. Unlike the HADS, the PHQ asks about physical symptoms of depression and suicidal thoughts, and is consistent with DSM IV definitions of depression. However, like other scales, definitive diagnosis should be established by clinical assessment. The scale can be self-completed, or administered with a clinician; it takes less than 3 minutes to answer for 85% of patients.<sup>253</sup>

In a sample of 3,000 adults in an American primary care setting, the PHQ had internal reliability of 0.89 and test-retest reliability of 0.84. ROC analysis showed an area under the curve of 0.95, suggesting that it discriminates well between people with and without major depression.<sup>253</sup>

### **3.6.2.3 Comparison of HADS and PHQ-9**

A summary of the characteristics of the HADS and the PHQ-9 is set out in Table 3-3.

	PHQ <sup>256</sup>	HADS	comments
Original paper		Zigmond & Snaith <sup>66</sup>	
Original setting	Primary care (US)	Medical outpatient clinic (UK)	
Subsequent evaluation	Medical, psychiatric and primary care (UK) populations Telephone completion <sup>258</sup> & epidemiological use (US)	Medical, psychiatric and primary care populations	NB Direct PHQ-HADS comparison in primary care in Scotland <sup>259</sup>
Scope	Depression only	Depression and anxiety	PHQ-anxiety also available
Time taken	2-3 minutes	2-5 minutes	
Criteria for illness	Yes (DSM IV criteria)	No 'within the normal range', or in a 'mildly', 'moderately' or 'severely' disordered state	Normative data for HADs from general population is available <sup>260</sup>
Number of items	9 (16 including GAD-7 for anxiety)	14	
Self complete	Yes	Yes	
Scoring	Items rated 0-3. Add items to generate summary score for diagnosis and/or assessment of severity	Items rated 0-3. Reverse scoring for 8 items then add to generate summary scores for depression and anxiety	
Cost	Free for clinical use	5- 50p/sheet	
Severity of illness	Yes (frequency of symptoms in previous 2 weeks)	Yes (assessment of symptom severity)	
Validity	Good	Good	Both measures have been extensively evaluated and have equivalent reliability, specificity, sensitivity <sup>259,261</sup>
Sensitive to change	Yes <sup>259,262</sup>	Yes <sup>259</sup>	

Table 3-3: characteristics of PHQ-9 and HADS

Comparison of the psychometric properties of the HADS-D and PHQ-9 was conducted in a Scottish sample of 1063 patients referred by their GPs to mental health workers with “mild to moderate mental health problems”. Both scales had satisfactory reliability, convergent/discriminant validity, robustness of factor structure, and were equivalent in their responsiveness to change.<sup>259</sup>

However there were significant differences between the scales in their thresholds for “caseness”, with the PHQ suggesting that patients had higher levels of depression than did the HADS. It is worth noting that the cut points used in the PHQ (depression rated as “minimal” (1-4), “mild” (5-9), “moderate” (10-14), “moderately severe” (15-19) and “severe” (20-27)) were chosen partly on the pragmatic basis that “they are simple for clinicians to remember and apply”, as well as the observation that changing cut points did not significantly affect the associations “between PHQ-9 severity and construct validity”.<sup>253</sup>

A study of 2,294 primary care attenders in England had similar findings.<sup>251</sup> Patients were assessed using one of three instruments: either the PHQ, HADs or BDI. Of 1658 patients tested with the PHQ, 83.5% were categorised as having “moderate to severe” (PHQ10 or more, HADS 11 or more) depression, compared with only 325 (55.6%) of the 584 patients assessed with HADS. The authors suggest that this is the threshold at which “active intervention” is usually considered, but scores above of 10-14 on the PHQ are considered to be “moderate” in severity and “watchful waiting” for at least a month is the recommended action.<sup>263</sup>

Despite these differences, doctors treated similar proportions of patients with antidepressants, suggesting that they did not rely heavily on the scale cut offs to make their decisions. This is in keeping with clinical guidance, which recommends that clinicians

consider other factors such as the degree of disability, previous history of depression, and patient preference when assessing the need for treatment.<sup>38</sup>

#### **3.6.2.4 Choice of depression scoring instrument for Doing Well**

The PHQ-9 was chosen for use in Doing Well for the following mix of practical and technical reasons.

- It was developed for use in primary care and has been validated in a Scottish primary care population
- It can be completed by either patient or clinician (typically the former in practice)
- It is quick to complete (three minutes or less)
- It has been validated for use in follow-up of clinical progress over time and able to be used for this purpose in practice
- It is free
- It was widely available to patients and staff online, and permission was given for it to be copied for clinical use after negotiation with the Copyright holder (Pfizer)
- GPs gave positive feedback about the measure during the initial pilot phase

#### **3.6.2.5 Clinical improvement and remission**

Rates of remission may be more clinically relevant than rates of improvement, since early and complete remission is associated with better function, a better prognosis at follow-up and more stable longer-term outcomes.<sup>264,265</sup> For this reason, remission has been proposed as a primary end-point for clinical trials.<sup>264</sup>

Primary care studies tend to have higher remission rates than trials with secondary care patients.<sup>266</sup> A meta-analysis of remission rates for major depression in primary care settings found 13 relevant trials. The trials used a range of depression assessments, and defined “remission” in relation to scores on those tools (no trial used the PHQ). Overall remission rates (regardless of type of intervention but excluding placebo or usual care arms) ranged between 50% and 67%. Remission rates were lowest (50%) for four trials of “programmed care”, (which included collaborative care using other health professionals and educational programmes intended to improve quality of prescribing). Active treatment with psychotherapy or pharmacotherapy in isolation had remission rates of 54% for each intervention. The best outcomes were seen in three trials of psychotherapy plus antidepressant treatment, with a 67% remission rate, although this category included one arm with only 35 patients.<sup>267</sup>

In the STAR\*D study of 3671 American outpatients with major depressive disorder, 56.1% of patients had achieved remission after two steps of treatment, with a “theoretical” cumulative remission rate of 67% after four steps in treatment assuming no drop-outs from treatment.<sup>265</sup> However this relatively high “theoretical” rate has been questioned by other authors.<sup>268</sup> A meta-analysis of outcomes in secondary care for trials of pharmacotherapy or psychotherapy (cognitive-behaviour therapy, interpersonal therapy, problem-solving and social work counselling) found remission rates of 46% for each form of treatment.<sup>266</sup>

### *3.6.3 Issues that Doing Well sought to address*

Previous sections have reviewed how depression is understood by patients and the public, and outlined how services organise their response. The evidence relating to pharmacological and psychological therapies for depression was also outlined. Before going on to consider how systems can make improvements to depression care, this section provides a brief overview of some of the problems that are acknowledged to challenge the NHS in its provision of depression care in Britain. Some of these issues have been introduced in the previous sections. The following were issues that we sought to address, at least in part, when designing the Doing Well service.

1. Clinicians and the public may conceptualise depression in different ways. Some people have difficulty in recognising their distress as a mental health issue, in acknowledging that this may benefit from professional help, and may not have ready access to accurate information about treatment choices. Patients have a “natural” reticence to discuss personal issues with professionals, and the particular stigma relating to mental illness reinforces this.
2. GPs vary in their propensity to identify depression cases, and there is widespread variation in prescribing rates of antidepressants. GP consultation length may militate against not just the detection of mental health problems, but also their management. GPs may not have the time, skill or system support to (for example) educate and “activate” patients into behavioural changes, or to use simple psychological therapies like guided self-help.
3. Concepts of depression developed and researched in specialist settings may translate poorly to the kind of problems seen in primary care. Some have argued that GPs emphasise “psychosocial context, stress, personality and coping” in their

management of mental health problems, compared with a more “categorical” and biomedical approach by psychiatrists,<sup>269</sup> though such a distinction would be disputed by psychiatrists.

4. There is limited access to specialist care for common mental health problems in Britain.<sup>7</sup> This is particularly true of access to psychological therapies; reports suggest that delays in accessing psychological therapies average six to nine months in England, and that waiting lists of up to two years are not uncommon.<sup>178</sup> Longer waiting times adversely affect engagement in therapy<sup>270</sup> and are associated with poorer patient outcomes.<sup>271</sup>
5. Care for people with chronic depression may lack the kind of structured, coordinated care and monitoring of outcomes that has been shown to benefit people with other chronic conditions. However, practice may be changing in the UK through the introduction of QOF targets. For example, ninety-five percent of available QOF points for depression were achieved by practices in Scotland in the year 2007-8.<sup>272</sup>

Bower and Gilbody endorse Shepherd’s view, first expressed in the 1960s,<sup>273</sup> that

“the cardinal requirement for improvement of the mental health services in this country is not a large expansion and proliferation of psychiatric agencies, but rather a strengthening of the family doctor in his therapeutic role”

and suggest that measures to involve secondary care may be more effective than those focussing on “education” or “liaison” with general practice.<sup>274</sup>



Doing Well sought to implement a form of service integration that was intermediate between primary and secondary care, retaining some aspects of each while functioning in a way that neither would conventionally recognise. The following section reviews the literature in relation to novel forms of service organisation.

### 3.7 Quality Improvement in depression care

Health care organisations have a responsibility to provide the best possible quality of care for their patients, but many people do not receive optimal treatment in practice. In an influential report, the American Institute of Medicine concluded that “between the health care we have and the care we could have lies not just a gap but a chasm”.<sup>275</sup>

The following description of routine deficits in depression care in the USA could equally apply to the situation in Britain:

“The gap between what we do in practice and what we know is very large. We insist that remission is our goal, yet we do not routinely carefully measure symptoms in practice to determine if remission occurs. Yet we know that “better but not remitted” consistently leads to a worse prognosis than full remission. We often underdose or poorly titrate medication. Finally, we often combine treatments in practice, yet very few trials have assessed either safety or efficacy of these efforts.”<sup>136</sup>

Quality improvement in healthcare is now recognised not only as a political and management imperative, but as an academic discipline in its own right. This section reviews some of the evidence relating to “generic” quality improvement in health care, before considering how these might be applied to care for people with depression. The evidence relating to quality improvement efforts in depression is then reviewed.

### 3.7.1 *Components of health service redesign*

Clinicians could be forgiven a degree of scepticism about the shifting fashions in models of health service management, not least since the methodologies themselves have often not been subject to rigorous evaluation:<sup>276</sup>

“The last two decades have seen the rise and fall of a number of concepts, ideas or methods in healthcare quality improvement (QI). We have progressed from medical audit to clinical audit and to clinical governance; from total quality management to continuous QI and to business process re-engineering; from statistical process control to six sigma and to lean thinking. At times, keeping abreast of the latest ‘new thing’ in healthcare QI can seem to require almost constant attention to the journals, conferences, books and training events in this field.”<sup>277</sup>

This thesis is primarily concerned with the influence of the Doing Well intervention on patients, rather than to assess how or why it might have affected health “delivery systems” in primary or secondary care. Yet quality improvement methodologies share common features, and successful interventions in one aspect of health care may be relevant to others. This section seeks to identify some common components of health service redesign, and to relate them to the approach taken by Doing Well.

The literature reviewed so far in this chapter was the evidence that informed the design and implementation of the Doing Well intervention. However it is widely acknowledged that “having the right information” is often insufficient to bring about change in clinical settings. Although health care systems sometimes respond spontaneously to new clinical evidence, change more typically takes place in an environment where interventions are complex,

clinical evidence is not clear-cut, responsibilities are ill-defined, and interventions are carried out by a range of disciplines over prolonged periods of time.<sup>278</sup>

### **3.7.1.1 Engaging stakeholders**

Engaging clinicians in change requires some understanding of group behaviour. For example, doctors have been characterised as a close-knit group of

“Intelligent individuals with egos of all shapes and sizes and once in senior positions they are not likely to readily respond to the requirements of others. They play from a power base of ‘expert knowledge’ supported by a network of colleagues and collegiate bodies. Their individual priorities may not be in harmony with organisational goals and predictably they will resent imposed change.”<sup>279</sup>

Effective engagement with GPs seems to require recognition of the skills and professionalism shared by primary care teams, and a practical recognition that participation in planning meetings represents costs to GPs in clinical time and money.<sup>279</sup>

Passive dissemination is an ineffective method of changing practice, but <sup>240</sup> change can be supported by the following activities:<sup>280</sup>

- the use of social-influence methods, such as local expert leaders
- feedback on performance is provided
- clinician workload is shifted to ancillary staff
- multiple practice-change strategies are used

### 3.7.1.2 Understanding the problem

Complex problems are by definition difficult to describe. A range of quality improvement tools have been described that allow for a relatively structured approach to understanding complex problems. These tools include cause/effect diagrams, process mapping or flowcharting, statistical process control, value streaming and comparative data analysis.<sup>277</sup> Many of these were promoted by the Centre for Change and Innovation in a review of evidence-based practice for service improvement for depression.<sup>281</sup>

### 3.7.1.3 Maintaining and generalising gains

Greenhalgh et al.<sup>248</sup> conducted a large systematic review of diffusion, dissemination and sustainability of innovations in health service delivery and organisation. Succinctly titled “How to Spread Good Ideas”, the review identified a number of characteristics that supported the adoption and spread of innovation. There was strong, direct evidence to support the following:

- **Relative advantage:** Clinicians will choose to modify what they do if they are presented with alternatives that are appropriate, fulfilling, and easier to accomplish than “standard” care. If stakeholders see no relative advantage, they tend not to consider the innovation further
- **Compatibility:** Innovations that are compatible with the values and perceived needs of a service will be more easily adopted and implemented
- **Trialability:** Innovations that can be experimented with by intended users on a limited basis will be more easily adopted and implemented.
- **Observability:** If the benefits of an innovation are visible to intended adopters, it will be more easily adopted and implemented.

### 3.7.2 *Models of service redesign in depression*

Depression is a major public health problem, and tackling it effectively requires interventions beyond the treatment of individuals:<sup>282</sup> “research demonstrates that treating depression is complicated and requires fundamental system redesign.”<sup>158</sup> Rather than describe every variant of service model, this section sets out some key themes that underly much of the literature on quality improvement in depression care.

#### 3.7.2.1 **“Complexity” in clinical systems**

Complexity is defined as “a scientific theory which asserts that some systems display behavioural phenomena that are completely inexplicable by any conventional analysis of the systems’ constituent parts. Reducing a complex system to its component parts may represent an ‘irretrievable loss of what makes it a system’”.<sup>283</sup>

The traditional response to complexity in clinical systems has been to reduce uncertainty with the use of linear, mechanistic metaphors. We commonly speak of care that is “delivered” to patients on “journeys” along “care pathways” organised by “service frameworks”. But the fluid, interactive meshes of decisions and behaviours in healthcare organisations is not well-served by such reductionist approaches. An alternative is to think of them as “complex adaptive systems”.<sup>284</sup>

This model accepts that clinical knowledge is often partial, that staff and patient behaviour may be irrational and unpredictable, and that the complex web of relationships that characterise health systems are constantly responding to their own feedback.

Rather than think about “resistance to change” in relation to staff or patient behaviour, we should think about what governs current practice, and try to identify “attractors”<sup>285</sup> that might encourage the kind of change we want. Qualitative studies of doctor-patient

interaction in relation to depression do not reveal lazy or ill-informed practice. Instead, they show doctors' well-intentioned (though not always successful) attempts to respond to their perceptions of patient needs and preferences.

Encouraging the rational use of antidepressants in this context may not be helped by more "education" about guidelines, but instead by a respect for the needs that are present in these consultations.

### **3.7.2.2 Complex interventions**

A substantial literature has emerged that describes alternative models of depression care, mainly based on studies from the USA.<sup>286,287</sup> Successful programmes typically require the implementation of complex interventions that bring about change in several areas simultaneously.<sup>288,289</sup> The most effective interventions seem to be those that rely on multifaceted, integrated programmes.<sup>288,290</sup>

In a systematic review of service delivery models for depression in primary care, Griffiths and Christensen<sup>291</sup> identified the following interventions as being effective in improving depression outcomes relative to control conditions:

1. "Care management: assistance within the practice in managing patient care (eg, the use of care managers such as a nurse to monitor and manage patients)
2. Enhanced/extended care: the use of specialist practitioners or the direct provision of enhanced therapy within the practice (eg, cognitive behaviour therapy provided by a health professional)
3. Guided self-help in general practice: the use of computer-based programs or other self-help materials supervised by a practitioner (eg, a nurse)

4. Systematic tracking by a non-doctor: monitoring of patient progress and/or provision of enhanced care (eg, by a nurse or psychologist)
5. Revision of professional roles: for example, a nurse assumes the role of case manager. Role shifting often involves greater involvement of non-health professionals in care delivery
6. Incorporation of patient preferences into care"

The following interventions were not effective: seeking to improve general practitioner training and feedback, involving the services of health professionals such as pharmacists, and linking services to mental health teams without proper infrastructure for follow-up.

### **3.7.2.3 Chronic care**

"Chronic care" is defined as "any condition that requires ongoing adjustments by the affected person and interactions with the health care system". Problems identified with chronic care include: rushed practitioners not following established practice guidelines, lack of coordination between different care workers, a lack of active follow-up, and insufficient training for patients to help them manage their illness well.<sup>292</sup>

Such a description applies to many people with depression, perhaps especially when their illness drains their motivation and hope: such a group is unlikely to respond well to conventional patterns of care in which follow-up is intermittent or at fixed intervals.<sup>73</sup>

Wagner<sup>293,294</sup> described a model for the management of chronic disease and gave examples of the changes to usual practice needed. The model envisages practice teams in productive interaction with informed, activated patients. Patient and clinician work collaboratively to identify the relevant problems, and jointly develop targets and treatment plans. Achieving this requires particular attention to improved "service delivery" systems, better clinical



information systems, and improved decision and self-management support for clinicians and patients respectively.<sup>295</sup>

#### **3.7.2.4 Stepped care**

Katon argued<sup>151</sup> that conventional health systems were ill-suited to the needs of people with chronic disorders like depression. In order to understand why and how to manage their chronic illnesses, patients needed additional support.<sup>296</sup> Optimal care would be “an interactive and iterative process between patients, their families and clinicians.”

Building on the “chronic disease model” familiar to general practitioners from the management of hypertension, asthma, diabetes and other diseases, Katon and others working in the Group Health Cooperative in the United States developed what they call a “stepped collaborative care” model for the management of depression.<sup>297-299</sup>

“Stepped care” describes an approach that minimises the intensity of the initial intervention for mild disorders. Systematic monitoring of outcomes permits “stepping up” to more intensive forms of treatment where clinical response is inadequate.<sup>79</sup> Stepped care models have been shown to be effective in the USA,<sup>297,298</sup> and were recommended for use in the management of depression in the UK by the National Institute for Clinical Excellence (NICE).<sup>26</sup>

Katon’s approach included four main components. Firstly, practice reorganisation created a register of people with depression and instigated proactive, flexible consultations, seeing people frequently during an acute phase and less frequently during remissions. Secondly, a range of materials were used to support patient education, and clinical practice guidelines were developed to aid diagnosis and the management of acute episodes, maintenance, and relapse. Thirdly, computer systems were established that recorded treatment and notified

staff when patient progress was not as expected. Finally, extensive use was made of assertive follow-up, particularly using telephone contact.<sup>73</sup>

Others have endorsed the use of algorithm-driven care and “disease management programmes” to improve outcomes.<sup>300,301</sup> Stepped care approaches have been estimated to have the potential to reduce the burden of depression by 10-30% by improving clinical outcomes.<sup>302</sup>

The MAPLE (Multiple Access Point and Levels of Entry) model was an adaptation of stepped care proposed for the delivery of cognitive behavioural therapy in the UK health system.<sup>303</sup> Believing that “services characterised by 9-5 working, hourly appointments and face to face therapy disenfranchise the majority of people who would benefit from CBT”, Lovell & Richards<sup>303</sup> proposed three broad levels of entry to services: wide delivery of CBT, for example through self-help approaches, simple focused interventions and complex specialist interventions.

### **3.7.2.1 Collaborative care**

Definitions of “collaborative care” vary, but this approach could broadly be described as a multifaceted organisational intervention designed to improve quality of care. Collaborative care models are based on the principles of chronic disease management,<sup>293</sup> and involve the integration of a number of elements into one “complex intervention”.

The implementation of collaborative care varies between centres, not least in the range of treatment intensities they involve. Some, but not all, models incorporate interventions such as screening for depression, scheduled telephone contact to encourage antidepressant compliance, structured psychological interventions with intensive follow-up, or enhanced use of information technology.<sup>287,304</sup>

Bower et al<sup>80</sup> helpfully categorise collaborative care interventions into three groups:

- (1) the introduction of case managers in primary care to support treatment;<sup>288,305</sup>
- (2) efforts to improve liaison between primary and secondary care with case workers receiving supervision from secondary care;<sup>298</sup> and
- (3) the introduction of methods to monitor and share information about the progress of individual patients

In a 2006 review, Gunn<sup>306</sup> emphasised the need for collaborative care to include a structured management plan (incorporating screening schedules and evidence-based treatment guidelines), scheduled patient follow-up to monitor treatment and progress, and mechanisms to improve inter-professional communication (such as team meetings, case conferences and shared clinical records).

A meta-analysis by Gilbody<sup>287</sup> identified 34 randomized studies of collaborative care in the provision of services for people with depression in primary care. The studies included a total of 12,355 patients with depression in primary care. Collaborative care showed significantly improved depression outcomes at 6 months, and there was evidence of longer-term benefit for up to 5 years. Effect size was directly related to medication compliance and to the professional background and method of supervision of case managers. The addition of brief psychotherapy did not substantially improve outcome, nor did increased numbers of sessions. Other meta-analyses have also supported the clinical effectiveness of collaborative care for depression<sup>286,301,306</sup>, though not necessarily their cost-effectiveness.<sup>306,307</sup>

Unfortunately, the applicability of these studies to primary care in the UK is limited. For example, twenty-seven out of 34 studies included in the Gilbody<sup>287</sup> meta-analysis were

located in the USA (where their effectiveness proved to be greater than in trials conducted elsewhere). In 18 trials, patients were specifically prepared to take antidepressant drugs and in 21 studies psychological therapies were not available as a treatment option. Since the service-level aspects of collaborative care will differ between health care systems, the effective transfer of service improvements into routine practice will relate to their adaptation to local needs and circumstances.<sup>308</sup>

The outcomes of recent UK-based randomised controlled trials of collaborative care for depression are outlined in the discussion.<sup>309-311</sup> Other trials of collaborative care for depression are underway in the UK,<sup>312</sup> the Netherlands<sup>313</sup> and Spain,<sup>314</sup> so our understanding of the optimal configuration and effectiveness of this model of care is likely to improve in future. Issues in generating, spreading and sustaining change

Once a new intervention has been implemented, it needs careful management to ensure that the changes can be maintained and spread. A review of the academic thinking behind the promotion of the “spread” of innovation in health care is beyond the scope of this thesis. But in simple terms, effective “spread” requires leadership (to set the agenda, make the case and accept responsibility for achieving the spread of ideas), good communication with potential and existing stakeholders, and an understanding of the relationships between the people who will be implementing the changes. Feedback about processes and outcomes is needed to monitor and adjust the response to spread as it progresses.<sup>315</sup>

Heifetz and Linsky argue that ‘the sustainability of the change depends on having the people with the problem internalising the change itself’.<sup>316</sup> This view is endorsed by May, who emphasises that “normalisation” focuses

“...on the conditions of use and the behaviour of everyday users rather than the special champions and early adopters so important to diffusion theories. It reflects the importance of stability, order, and practicability in professional and organizational behaviour in healthcare.”<sup>317</sup>

A complex intervention that is completely “workable” becomes embedded into the routine of everyday healthcare activity, without disruption to the social relations and behaviour around it. May *et al* call this kind of successful assimilation “ecological success”,<sup>318</sup> and argue that it is achieving this state of integrated “normalisation” that represents successful change, rather than achieving clinical or cost-effectiveness.

According to this model, decision-makers in health care must consider two aspects when introducing a complex intervention: the workability, clinical and cost effectiveness of the change, and its capacity for successful integration into existing or new configurations of health services and professional practice.<sup>317</sup>

### 3.8 Summary

Depression is a common condition, though one which is difficult to categorise or describe. The causes and treatments for low mood are often poorly understood by the general public, and it can be difficult for GPs and patients to align their needs in the dynamic of the consultation

Service responses to depression have traditionally been organised on fixed, tiered models of care that are closely aligned to professional and service structures. “Stepped care” models are still being refined, but depend on smooth transitions between types of care and quality feedback about response to treatment.

The efficacy of antidepressants, especially in mild depression, is complicated by a powerful “placebo” effect, and the tendency of depression in community settings to remit spontaneously over time. There may be some potential for services to harness “non-treatment specific” factors, and minimal or “containing” interventions may be sufficient for many patients whose symptoms may remit without treatment.

There is good evidence for the effectiveness of psychological therapies, though matching the duration, intensity and modality to the needs of individual patients may be difficult – and their resource-intensive nature makes it difficult to provide easy access.

Influencing practitioners to change their clinical behaviour can be difficult, but systems which achieve this successfully are likely to do so by paying attention not only to information, “flow” through systems but also to the motivations and incentives that act to influence behaviour in systems.

The following sections describe the implementation and outcomes of these factors as they apply to the Doing Well intervention in Renfrewshire.

## 4. Methods

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### 4.1 Setting

The Doing Well programme was implemented in 14 general practices in Renfrewshire, Scotland. This is a mixed urban-rural area with pockets of significant deprivation, located about 10 miles south-west of Glasgow.

The map in Figure 4-1 shows the geographical area covered by the Renfrewshire Community Health Partnership. The Doing Well intervention took place in practices covering the western part of this area.

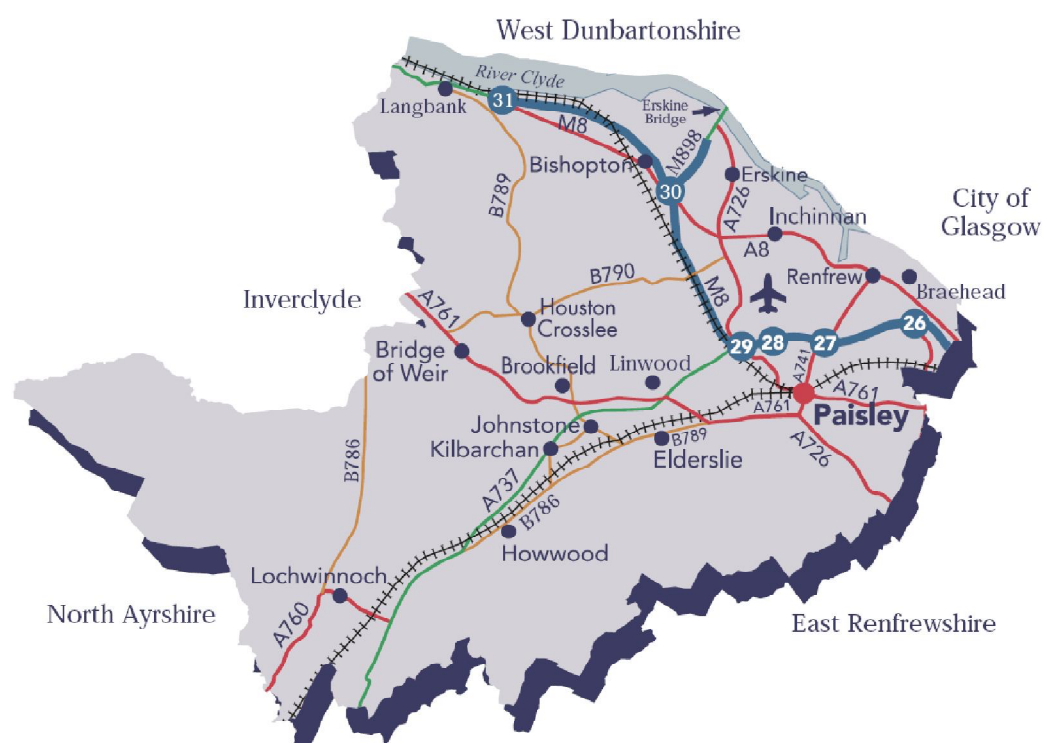


Figure 4-1: map of Renfrewshire Community Health Partnership area

The Renfrewshire Community Health Partnership covers a total of 30 GP practices with a total practice population of 177,548 people (at October 2006). The CHP area also includes 30 dental practices, 44 pharmacies and 20 opticians.

The age profile of the Renfrewshire population is not significantly different from that of the Scottish population. Table 4-1 summarises some health and economic parameters for Renfrewshire Community Health Partnership.<sup>319</sup> People from ethnic minorities accounted for 1.2% of the total population of Renfrewshire in 2001, compared with the Scottish average of 2.0%. Life expectancy during 2001-5 was 72.5 years for men and 78.3 years for women, which is within two percent of the Scottish average.

The Scottish Index of Multiple Deprivation (SIMD) is the official tool used by the Scottish Government to identify concentrations of multiple deprivation in small areas (called “data zones”) across Scotland. This provides a relative ranking of 6,505 such data zones in Scotland from the most deprived (ranked one) to the least deprived (ranked 6,505).

The Index is derived from 38 indicators across 7 domains (income, employment, health, education, skills and training, housing, geographic access and crime). Each domain is allocated a weighting based on the relative importance of the domain in measuring multiple deprivation, and the robustness and availability of the data. The Index is then comprised of a weighted sum of the seven domain scores. For example, the domain weightings used in the 2009 SIMD (expressed as a % of the overall weight) are: current income (28%), employment (28%), health (14%), education (14%), geographic access (9%), crime (5%) and housing (2%).<sup>320</sup>

Renfrewshire is slightly more materially deprived than the Scottish average: 17% of the population of Renfrewshire live within the 15% most deprived postcodes in Scotland in



2006. Fourteen percent of the population are “employment deprived” (the proportion of the working age population who are unemployed or are not involved in the labour market due to ill health or disability), which is 8% higher than the Scottish average. Eleven percent of the population claim incapacity benefits and 21% of the population have a long-term limiting illness (10% and 3% above Scottish averages respectively).

Eleven percent of people in Renfrewshire classify their own health as “not good”, compared to the Scottish average of 10.2%. Suicide rates during the period 2001-5 were 15.4 deaths per 100,000 population, which is similar to the Scottish average. Nine percent of people are prescribed drugs for anxiety and depression, compared with the Scottish average of about eight percent.

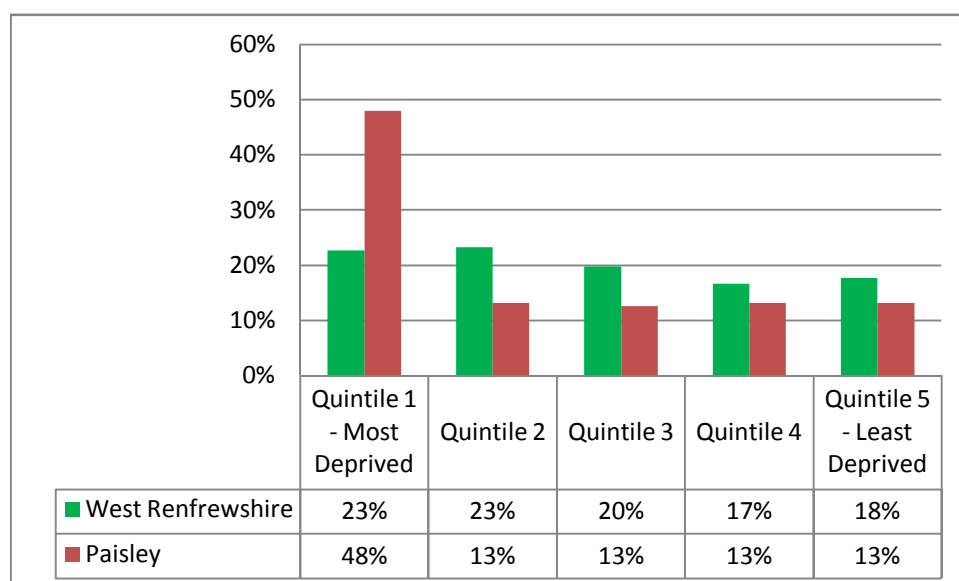
Indicator	Number	Measure	Relation to Scottish average	Time period
<b>Male life expectancy</b>	72.5	years	-2%	2001-5
<b>Female life expectancy</b>	78.3	years	-1%	2001-5
<b>Minority ethnic groups</b>	2,139	1.2%	-38%	2001
<b>Suicide rate (standardised for age and sex)</b>	134	15.4/ 100,000	-2%	2001-5
<b>Self-assessed health “not good”</b>	18,853	10.9%	+7%	2001
<b>Incapacity Benefit &amp; SDA Claimants</b>	11,305	10.5%	+10%	2007
<b>Long-term limiting illness</b>	36,272	21%	+3%	2001
<b>Prescribed drugs for anxiety or depression</b>	15,987	8.8%	+9%	2006
<b>Income deprived</b>	25,356	14.9%	+7%	2006
<b>Employment deprived</b>	14,748	13.9%	+8%	2006
<b>Social grade E</b>	31,310	22.8%	+2%	2001
<b>Households without access to car/van</b>	28,030	37.2%	+9%	2001
<b>Adults without qualifications</b>	42,968	33.6%	+1%	2001

Table 4-1: Community health and wellbeing profile for Renfrewshire Community Health Partnership (total population 169.600 in 2007)

Twenty-three percent of the population are in social grade E (on benefits, unemployed or in the lowest grade work). Thirty-seven percent of the population do not have access to a car (nine percent higher than Scotland as a whole).

There are 30 GP practices in Renfrewshire Community Mental Health Partnership. Although now managed as one group, a previous management arrangement allocated these practices to one of three Local Health Care Cooperatives (LHCCs): Paisley LHCC, West Renfrewshire LHCC and Renfrew LHCC. Investment in the Paisley LHCC had improved the provision of community mental health services, but when the Doing Well intervention was being planned in 2003, community services were very limited in West Renfrewshire and Renfrew. It was therefore decided to implement the Doing Well pilot in West Renfrewshire, which comprised 14 practices.

There were significant differences in the profile of deprivation in West Renfrewshire and Paisley (the other part of the Renfrewshire Community Health Partnership). Figure 4-2 shows that almost half of the population of Paisley lives in the most deprived quintile of the Scottish Index of Multiple Deprivation, whereas the population in West Renfrewshire is more evenly spread between quintiles of deprivation.



**Figure 4-2: percentage of population living in quintiles of deprivation for West Renfrewshire and Paisley**

## 4.2 Recruitment of participating practices

The fourteen local practices in the previous West Renfrewshire LHCC were invited to attend an information evening held in June 2004. At least one representative from each eligible practice attended that meeting. Practices who might be interested in joining the Doing Well programme were asked to register their interest, and told that they would be contacted at a future date. The fourteen practices were told that their participation in the programme required them to meet three criteria:

1. to make all referrals using the electronic referral system described in section 4.4.1
2. to include a depression assessment using the Personal Health Questionnaire (PHQ, section 4.8.1) with every referral

3. to provide a consulting room where Doing Well staff could see patients referred from that practice.

All fourteen practices were able to meet these requirements, and all fourteen registered their interest. One practice was chosen to pilot the intervention between July and October 2004, and then other practices were gradually invited to join the programme thereafter. The dates that practices were recruited to the programme are outlined in Table 4-2.

Practice	List size	Date joined Doing Well
1	10,058	Jul-04
2	4,841	Nov-04
3	6,553	Feb-05
4	6,751	May-05
5	2,661	Jun-05
6	4,351	Jun-05
7	4,992	Jul-05
8	8,270	Aug-05
9	6,034	Aug-05
10	2,069	Oct-05
11	5,908	Oct-05
12	3,230	Oct-05
13	6,051	Dec-05
14	4,244	Feb-06
total	76,013	

**Table 4-2: date of practice recruitment to doing well**

By February 2006, the Doing Well recruitment target of 14 practices in West Renfrewshire was reached (a total of 76,013 registered patients).

### 4.3 Referral criteria

Doing Well accepted GP referrals of new presentations of low mood, depression, mixed anxiety and depression or adjustment disorder from participating practices for people aged between 18 and 64 inclusive. There was no “threshold” of severity for referral to secondary care, meaning that Doing Well would see any patient who met referral criteria, no matter how mild or severe their mood problems were.

“New” presentations were defined as people who had not sought professional help with affective symptoms in the previous six months, even if they had experienced mood problems before that time. A presentation was still considered “new” if the patient had begun GP treatment for depression within the preceding two months. This meant that GPs had some latitude to begin treatment for depression without having to refer to Doing Well immediately. Although Doing Well aimed to see new patients promptly, people requiring emergency assessment and treatment were referred to secondary care psychiatric services.

Patients were not accepted onto the clinical Doing Well programme if they had the following problems:

- A primary alcohol problem
- A primary drug problem
- A primary anxiety problem (significant comorbid anxiety was not an exclusion criterion)
- Depression presenting as part of bipolar affective disorder
- People with a terminal illness
- People with medical or psychiatric emergencies

- Current psychosis
- Significant cognitive impairment

Although accepted for clinical care, people who were pregnant at the time of referral or who could not read English sufficiently well to use the self-help materials were not included in the evaluation of the service. This was because their treatment may have needed to deviate significantly from the research protocol in order to meet their needs.

Suicidality was not an exclusion criterion, but high current risk of suicide was an indication for prompt referral to secondary care mental health services by the Doing Well team.

People mistakenly referred to Doing Well who met exclusion criteria for the clinical service were either directly passed on to more appropriate services by Doing Well staff, or a discussion was held with the referrer to expedite a more appropriate referral.

## **4.4 The Doing Well intervention**

### *4.4.1 Referral process*

The Scottish Care Information Gateway (“SCI Gateway”) is a national system that integrates primary and secondary care systems using secure Internet technology. All patients were referred by their general practitioners, using this system to link primary care electronic records with those in secondary care. Doing Well worked with software programmers at the Scottish Care Information Gateway to integrate the Personal Health Questionnaire into the online referral form. Clinicians were then asked to complete the online PHQ with the

patient; provision was made on the form for any brief additional information the GP might choose to add. Once the form was complete, the software would extract relevant information from the primary care system, and transfer it electronically to the *Continuum* system used in secondary care by Doing Well.

Figure 4-3 shows a screenshot of the software as it appeared on the GP's referral screen.

**Assessment**

Please complete and score all questions using the figure af  
Questions apply to symptoms over the last 2 weeks

Little interest/pleasure doing things (Please Specify)

Feeling down, depressed, hopeless (Please Specify)

Trouble falling/staying asleep, sleeping too much (Please Specify)

Feeling tired / having little energy (Please Specify)

Poor appetite or overeating (Please Specify)

Feeling bad about yourself (Please Specify)

Trouble concentrating on things (Please Specify)

Moving or speaking slowly / fidgety or restless (Please Specify)

Thoughts; better off dead, of self harm (Please Specify)

If problems; how difficult to work; to take o (Please Specify)

If Problems (Please Specify)

Cancel Attach

**Figure 4-3: screenshot from GP SCI screen showing referral form; "callout" box shows detail of PHQ online questions**

Occasionally exceptions were made when the electronic system could not be used; in these instances, paper referrals were accepted to minimise disruption and ensure patient needs were not compromised. The information was then manually transferred into the electronic system.

Clinical and support staff in general practice received training in the use of the electronic referral system and assessment tools.



GP referrals were required to include the following information:

1. Name
2. Age
3. Date of birth
4. Community Health Index Number (CHI: the standard patient identifier used throughout the NHS in Scotland)
5. Postal address with postcode
6. Contact telephone number
7. Email if available
8. PHQ with individual scores for each question
9. Current medication
10. Brief past medical and psychiatric history (extracted from GPASS problem list)
11. Brief text about presenting problem where GP feels this is appropriate

Inclusion of the PHQ was mandatory. All referrals therefore included an assessment of depression severity using the Personal Health Questionnaire (PHQ) at the time of referral.

GPs were asked to give all referred patients a copy of the Doing Well information leaflet.

After a referral was received by Doing Well, patients were contacted directly by post. They were sent an information pack, which contained the following material:

- An introductory letter detailing appointment date, time, venue and name of clinician
- An information leaflet about the service
- An information leaflet about depression (from the Royal College of Psychiatrists)
- Information on the evaluation of the service
- Consent form (to allow this to be read before the first appointment)

- A copy of the assessment scales used by Doing Well: the PHQ (Personal Health Questionnaire), EQ5D and Work and Social Adjustment Scale (WSAS)

The letters, information leaflets, consent form and assessment scales described above are available in the Appendix beginning at section 10.2. Patients were not required to complete the assessment scales prior to appointment, but they were included in the pack so that they could become familiar with them prior to attending their first appointment.

Patients referred to the service were asked to confirm in writing or by phone that they wished to attend, and only those who responded were offered an initial appointment.

Assessments were intended to be completed within two weeks of referral, though sometimes patient preferences and availability or staff absence caused the first assessment to be delayed.

The PHQ noted at referral was the main determinant of care. People with a PHQ of less than 15 (indicating “mild” or “moderate” depression) were allocated to initial assessment by the self-help support worker, and those with a higher score were initially allocated to a primary care liaison worker. However each referral was reviewed individually, and patient preference or clinical judgement could “overrule” this allocation where appropriate.

Clinical information was gathered at each visit, and recorded in *Continuum*, the standard electronic record-keeping system used by South Clyde Mental Health services.

#### 4.4.2 Consent

All patients included in this study gave written consent for their anonymised data to be used as part of this evaluation. Consent to involvement in the evaluation was recorded on every

patient's electronic case record. Non-consent to participation in the evaluation did not influence clinical care in any way. Ethical approval for the study was granted by the Greater Glasgow and Clyde Local Research Ethics Committee (Ref AC04/073).

All service users had the rights of privacy under the Data Protection Act (1998). Any unauthorised disclosures were potentially in breach of Section 55 of the Act. Individual staff members were also bound by the requirements of their professional body, with guidelines on matters of confidentiality clearly stated in the codes of practice. Each individual member of the Doing Well team was held accountable for his or her own practice in relation to confidentiality. In addition, all NHS Staff are governed by the NHS Scotland Code of Practice for patient confidentiality.

#### *4.4.3 Staff roles*

The function of the self-help support worker was to help people who have adjustment problems or mild to moderate depression to deploy appropriate coping skills and use guided self-help techniques to manage their low mood. Contact included telephone support and email-based contact where appropriate. The care protocol for self-help support workers is set out in appendix 10.7.

Self-help support workers recruited to the programme had little previous clinical experience and were therefore not employed to generate treatment plans or to act as a therapist. Instead they used an operationalised protocol that set out a series of tasks that they were intended to work on to support the patient. In practice, the psychology assistants recruited to these posts were accomplished and ambitious psychology graduates who were keen to gain clinical experience.

The function of the primary care liaison worker was to provide support and help to people with moderate to severe depression. In addition to the tasks carried out by the self-help support worker, the primary care liaison worker was responsible for the following interventions:

- Self-help support with the same materials, but with recognition of the increased level of distress and complexity that may be present in this patient group.
- Development of appropriate care plans in conjunction with the patient
- Provision of brief Cognitive Behavioural Therapy, Interpersonal Therapy or brief psychodynamic psychotherapy for practitioners with these skills. These forms of psychotherapy were chosen because they have an established evidence base, could be conducted during relatively brief interventions and were areas in which staff either already had accredited training or could be supported to acquire these skills
- Make recommendations to GPs about antidepressant prescribing, after case discussion with the Doing Well psychiatrist where appropriate
- Provision of information to patients about antidepressants
- Close monitoring of any prescribed antidepressants, including assessment of concordance and review of any potential side effects

The care protocol for primary care liaison workers is set out in appendix 10.8 on page 303.

Governance of clinical safety and quality was achieved by measuring patient clinical outcomes, monitoring “process-related” aspects of treatment (like caseload, number of contacts, medicines use) and ensuring that a proportion of all cases were discussed openly at group supervision.

Experienced staff members were encouraged to modify their approach in response to individual patient need. These clinicians were encouraged to be open about any gaps in their skills or knowledge and to address any perceived deficits using the time available to them for continuing professional development.

The primary care liaison worker posts proved to be popular when they were advertised, and it was possible to recruit high-quality candidates to the role. Staff appointed typically had more than ten years of clinical experience, which included a strong interest in psychological approaches to treatment (even if they did not have formal qualifications in this area). Doing Well was recognised locally to be an innovative project and was therefore likely to attract staff who were enthusiastic and progressive.

#### *4.4.4 Clinical interventions*

Patients were seen in their local health centre, where first assessments were scheduled to be of about 50 minutes duration. Patients referred with a Personal Health Questionnaire (PHQ) score less than 15 were allocated to a less intensive treatment programme based on guided self-help, whereas those with a score of 15 or more were allocated to a treatment programme that could access a range of pharmacological and psychological treatments in addition to guided self-help. These cut-off points are based on the original evaluation of the PHQ<sup>253</sup> and subsequent guidance on its use,<sup>321</sup> as discussed in section 3.7.2.3.

All assessments included an evaluation of presenting symptoms, current social and work functioning, and previous personal, family and medical history. Clinicians enquired about other symptoms of mental health problems and of the patient's expectations of treatment.

The GP referral automatically included a list of current medication, and this was checked for accuracy with the patient.

All patients were introduced to self-help materials based on the “Overcoming Depression” text.<sup>194</sup> The choice of materials and broader issues relating to the guided self-help approach were discussed in the literature review in section 3.5, page 90. “Guided self-help” of this kind was conducted in accordance with local training in “Practical Psychological Skills” mentioned above. Lifestyle advice with respect to exercise and alcohol use was given to all patients.

The Personal Health Questionnaire was used to track progress over time, and non-responders were “stepped up” to more intensive forms of treatment if needed. An “adequate” response was considered by Doing Well to be a reduction in PHQ score of five or more,<sup>321</sup> or a reduction in total score of 50% or more,<sup>322</sup> but in practice clinicians used this figure as a guide while exercising their own clinical judgement about an appropriate interpretation of response.

Since patient recovery may not always correlate with a reduction in symptoms, a PHQ score might sometimes misrepresent a patient’s progress or mental state. For example, a patient might describe an increase in PHQ score while they tackled distressing issues in therapy, or continue to have poor sleep and appetite despite a significant improvement in social or work functioning.

The “steps” in care are represented diagrammatically in Figure 4-4.

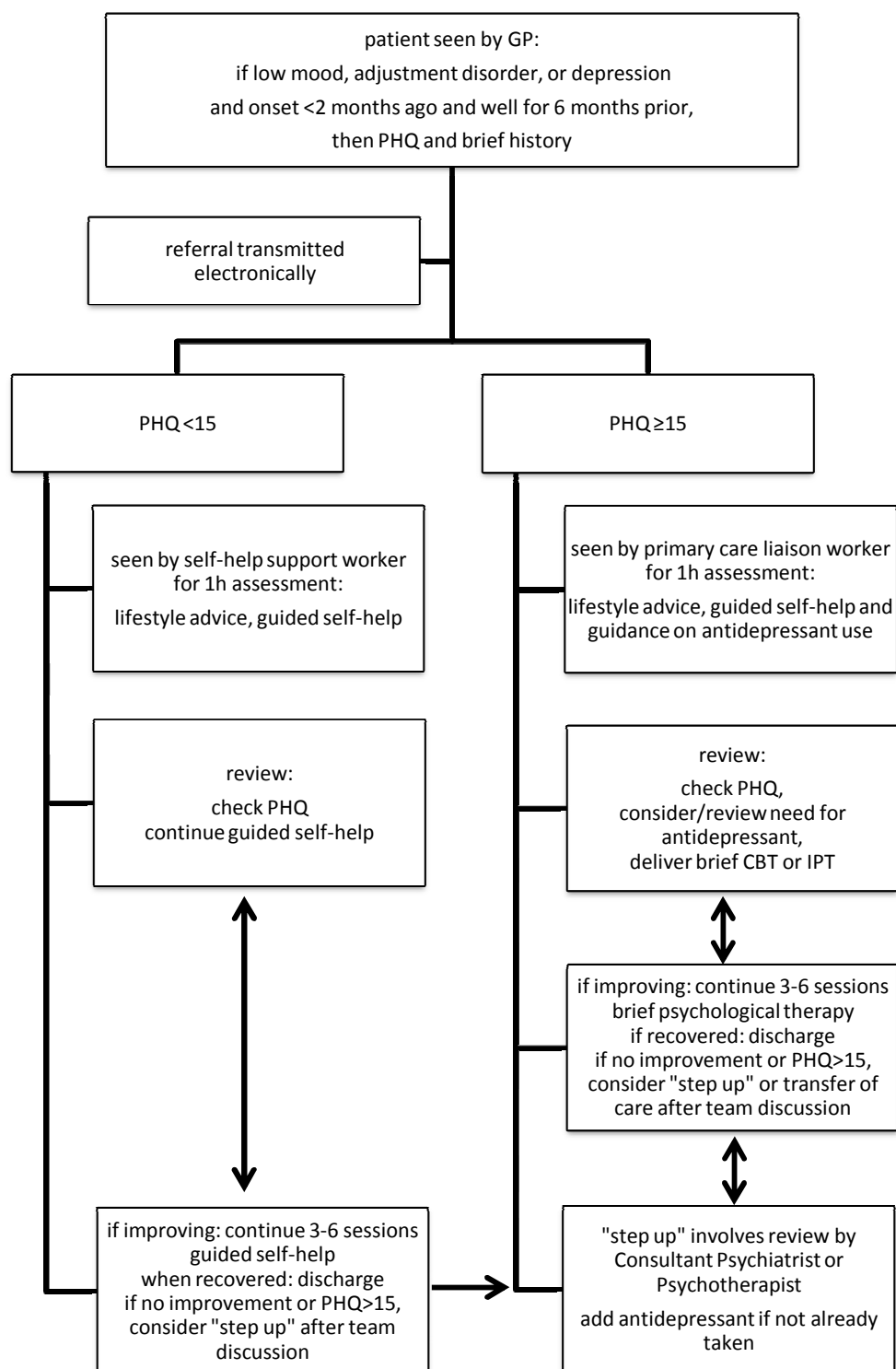


Figure 4-4: schematic representation of “steps” in care related to response to treatment

An assessment of suicidal ideation was included at each review point. All patients would continue with the planned self-help intervention, as long as they showed an adequate clinical response.

#### *4.4.5 Prescribing*

Antidepressant treatment was recommended for patients scoring 15 or more on the PHQ, or who had a PHQ greater than 10 and had not shown improvement in mood with previous treatment during this episode of care. This treatment protocol was based initially on the recommendations of the MacArthur Initiative on Depression in Primary Care in the USA.<sup>263</sup>

Antidepressant treatment recommendations were made in keeping with a 3-drug local formulary (fluoxetine, citalopram or lofepramine). Work to promote the use of the local antidepressant formulary was undertaken in collaboration with the Prescribing Advisors for NHS Greater Glasgow and Clyde. The development of the formulary in early 2004 used the evidence available at the time, which suggested that all antidepressants were of equivalent efficacy. A view was taken that it was sometimes helpful to try a drug of a different class where the initial agent had been ineffective. On this basis, the cheapest available Selective Serotonin Reuptake Inhibitors (SSRIs) were chosen (fluoxetine and citalopram) and the tricyclic lofepramine added since it was a different drug class, and considered relatively safe if taken in overdose. Particular attention was paid to patient information and education with regard to medicines. Education and support for primary care staff in relation to prescribing is described in more detail in section 4.7.2.



## 4.5 Discharge and follow-up

Once a period of treatment was considered to be complete by the team, patients were formally discharged. In order to discharge a patient, the relevant clinician would:

- Record discharge status in patient's electronic record
- Use the electronic record to produce a written discharge letter detailing length and type of treatment and send this to the patient's GP with a note of any other services used or referred to
- Inform patients that they were free to self-refer to the Doing Well team for up to six months after discharge and encouraged to use the PHQ again themselves if they had concern about deteriorating mood.
- Give the patient a "discharge pack" of measures and ask that they complete the Work and Social Adjustment Scale, the EQ-5D and Client Satisfaction Questionnaire. Recognising that it might be difficult for patients to give unbiased answers to the latter questionnaire when the clinician was present in the room, patients were invited to complete the measures in the waiting room or at home, and provided with a stamped addressed envelope (if required) to return the questionnaires.
- Four months after discharge, the team administrator sent participants the following measures as a "follow up" assessment: the PHQ, Work and Social Adjustment Scale, the EQ-5D and Client Satisfaction Questionnaire. A stamped, addressed envelope was provided to return the measures to the team. At least one reminder letter or phone call was sent to each non-responding patient.

This approach to discharge was used because a programme based on brief interventions for large numbers of people needs to maintain a "flow" of patients through the system. Doing

Well did not necessarily need to maintain contact with all patients until they had recovered, although this did happen for many people. Instead, the goal of the service was to provide people with the tools and confidence to begin to get better, and to be able to manage their ongoing recovery themselves. Patients were therefore discharged as soon as it was felt that they could recover on their own, even if they were not fully well. Patients who needed longer-term or other treatments were transferred to appropriate services as soon as their needs became clear.

Maintaining the safety and clinical appropriateness of these rapid patient “flows” required the service to be readily accessible to people who ran into unexpected difficulties after discharge. It was considered important that they could arrange further treatment with their key worker through phone or email contact, without having to negotiate access through their GP or other parts of the service.

For those who did not attend (DNA) or disengaged from treatment (left treatment before agreed sessions had been completed), the relevant clinician would try to contact the patient to ask about the reasons for their disengagement.

## 4.6 Staff training and skill mix

The Doing Well team consisted of the following staff (Figure 4-5):

staff	WTE	notes
Self-help support worker	1.0	One full time psychology assistant with additional clinical training
Primary care liaison worker	4.5	3.5 WTE Psychiatric nurses and 1.0 WTE occupational therapist
Consultant psychiatrist	0.2	
Team manager	0.5	Remaining 0.5 WTE of this post included in clinical sessions as primary care liaison worker above
Team administrator	1.0	

**Figure 4-5: staff employed by Doing Well**

The self-help support workers were psychology graduates who received local training in “Practical Psychological Skills”. This is a skill-based course lasting 30 hours which trains practitioners to use the self-help book “Overcoming Depression: A Five Areas Model”,<sup>194</sup> as described in section 3.5.1.1 of the literature review. Their work was clinically supervised both by senior Doing Well clinicians, and by the local psychology department. Total individual clinical supervision amounted to two hours per week.

Primary care liaison workers were experienced psychiatric nurses or occupational therapists with expertise in mental health. They were trained in the use of guided self-help techniques, but had additional training in Cognitive Behavioural Therapy and/or Interpersonal Therapy and the pharmacological treatment of depression. A consultant psychiatrist (the author) was part of the team, acting to review more complex clinical cases, and to supervise other clinicians. This amounted to 8 hours of clinical input per week.

Each non-medical "Doing Well" clinician worked to a timetabled 10-session weekly "template" that comprised of:

- 1-2 sessions administration
- 1 session of group supervision
- 5-6 sessions of direct patient contact
- 2 sessions professional development

"Professional development" sessions were allocated to a range of tasks, depending on a shared assessment of staff members' training needs and preferences.

Weekly clinical supervision was conducted in group format, involving all Doing Well clinicians. These meetings were held to review clinical cases and individual staff workload. Doing Well information systems allowed for the ready identification of patients who were not responding to treatment and needed a change in their care. The workload for individual clinicians (number of cases, duration of treatment, number of contacts per patient) could also be monitored and amended as necessary.

Doing Well staff worked in collaboration with the primary care team who retained overall responsibility for prescribing and for the physical health care of people referred to the Doing Well programme.

All staff members were required to meet their professional responsibilities in relation to their duty of care to patients as set out in professional codes of conduct and registration requirements. Staff also had a professional obligation to recognise and observe the limits of their training and competence, and to be sure that anyone else to whom Doing Well staff

may refer was also appropriately qualified and competent. These aspects of clinical governance were emphasised during induction and ongoing team development.

## 4.7 Education and support

A range of “educational” activities was undertaken by Doing Well to support the implementation and development of the programme. These educational activities are described below.

### 4.7.1 *Doing Well staff*

“Professional development” sessions were allocated to a range of tasks, depending on a shared assessment of staff members’ training needs and preferences. Examples of professional development undertaken by different staff members included

- Completing a 2-year diploma course in cognitive-behavioural therapy
- Going on a 1-year secondment to a department of psychotherapy
- Completing a course in Interpersonal Therapy
- Attending a conference in primary care mental health
- Writing or analysing research papers
- Developing group work teaching materials
- Going on a 2-day course on “mentalisation” approaches to psychotherapy
- Training in website development

In addition, self-help support workers (who were recruited as graduates in psychology) were allocated to spend 2 sessions per week in the local psychology department, where they took on a small caseload and received one hour direct supervision from clinical psychologists each week. Quarterly meetings for all Doing Well staff were held away from base in order to review performance data and review or formulate protocols and standards for the clinical service.

#### 4.7.2 *Primary care staff*

Prior to formally joining the Doing Well programme, the software required to make electronic referrals was installed in practices (where this was required) and training was offered to practice staff in the referral system.

Between July 2004 and October 2006, three evening meetings were held to which all GPs in Renfrewshire were invited (roughly double the number of GPs already participating in the Doing Well programme). These evening meetings combined “didactic” teaching in relation to depression management and antidepressant use from local/regional clinical and academic speakers with information about the progress of the Doing Well programme and an opportunity to share feedback from primary care.

The formulary was rewritten to give advice on non-drug approaches to depression treatment, to emphasise the use of the PHQ to assess depression severity and to give advice on using the minimum effective dose of any antidepressant. These messages were reinforced by practice visits throughout Renfrewshire by Prescribing Advisors from the Health Boards and by ongoing contact with Doing Well staff amongst participating practices.

The formulary message was supported by the “marketing” by Doing Well of a fictional drug called “FluCitamine” to local GPs and secondary care (Figure Figure 4-6). “FluCitamine” was actually a mnemonic device to remind prescribers of three formulary choices, and was presented to them in a light-hearted way. “FluCitamine” summarised “NICE guidance on a pen”. Seven words conveyed a serious message: PHQ assessment should be used to support prescribing of one of three formulary drugs for more severe depression only. These activities were made available to all Renfrewshire practices, not only those participating in Doing Well.



**Figure 4-6: "marketing" logo to promote reminder about formulary antidepressant use**

The Doing Well logo and website address was used on all communications and also distributed on promotional mugs to local GPs and other stakeholders (as shown in Figure 4-7).



**Figure 4-7: Doing Well logo and contact details**



### *4.7.3 Patients and the public*

A range of printed materials were prepared to support the Doing Well programme. These included an information leaflet about Doing Well and depression, and local copies of the PHQ that included information about local resources on the reverse side of the measure.

A website at [www.doingwell.org.uk](http://www.doingwell.org.uk) was written which included an online version of self-assessment using the PHQ, downloadable copies of the PHQ, information about depression and “user stories” from people who had benefited from the programme. The website was launched by Douglas Alexander, a Member of Parliament for the local area.

Doing Well received media coverage from the Scottish national newspaper “The Herald”, the Scottish national newspaper “The Sunday Post”, the TV news programme “Reporting Scotland”, and other publications. Doing Well was also featured on local radio stations “Q-FM” and the community radio station “Foxbar Radio”.

Two 8-session courses in self-help using a Cognitive Behavioural Therapy approach were delivered by Doing Well staff at a local Further Education College in 2006. Both courses were over-subscribed. A range of books, including self-help books, relating to depression were purchased for local libraries and a shared publicity event to promote their use was held with the Libraries Service of Renfrewshire Council.

## 4.8 Outcome measures

### 4.8.1 *Clinical outcomes in participating patients*

Four outcome measures were intended to be used to manage clinical care within Doing Well and to assess the outcomes of the programme. The measures were as follows.

1. The Personal Health Questionnaire<sup>256</sup> (“PHQ”, completed at referral and each subsequent contact)
2. The Work and Social Adjustment Scale<sup>323</sup> (completed at assessment, discharge and 4-month follow up)
3. The EQ-5D,<sup>324</sup> completed at assessment, discharge and 4-month follow up.
4. The Client Satisfaction Questionnaire<sup>325</sup> (completed at the end of treatment and at 4-months follow-up)

Each of these measures is reproduced in the format they were presented to patients in Appendix 10.5.

The PHQ is a self-administered nine-item scale capable of producing a depression rating consistent with the Diagnostic and Statistical Manual of Mental Disorder 4<sup>th</sup> edition (DSM IV). The reasons for choosing this clinical outcome measure, and other details regarding its validity and reliability were set out in section 3.6.2.4.

The Work and Social Adjustment Scale<sup>323</sup> is a self-complete instrument that asks about functioning in five domains: at work, at home, in “social” and “private” leisure activities and in close relationships. Originally a 4-item scale (work, home, social, and private leisure) used to rate disability in phobia research, Mundt et al<sup>323</sup> adapted it to measure the outcome of most patients in treatment and later added its fifth item concerning interpersonal relations.

The measure was chosen for this study in order to measure functional impairment relating to depression. The scale is simple, sensitive and reliable and has been validated for use in a primary care population.<sup>323</sup>

The EQ-5D is a standardised instrument for use as a measure of health-related quality of life. Developed by researchers from seven countries in the “Euroqol” group (including the UK), the EQ-5D includes five 5-level dimensions: morbidity, self-care, usual activities, pain and anxiety/depression. It is applicable to a wide range of health conditions and treatments, and provides a simple index value for health status. The measure is designed for self-completion by respondents and can be used in postal surveys, in clinics and face-to-face interviews. It is cognitively simple, and takes a few minutes to complete. Population norms have been published for a range of countries, including the UK.<sup>326</sup>

The Client Satisfaction Questionnaire (CSQ)<sup>325</sup> is an 8-item self-completed measure that is able to provide a brief, standardised assessment procedure applicable to a range of service settings. It is designed to be a direct measure of an patient’s personal experiences with a service, rather than with health care services in general.<sup>327</sup> The measure has been shown to have high internal consistency, and to relate to change in client-reported symptoms.<sup>328</sup>

Although patients completed each of these measures, this research used only the PHQ to assess clinical outcomes in practice. The Work and Social Adjustment Scale, EQ-5D and Client Satisfaction Questionnaire were completed as part of the standard assessment by Doing Well staff, and completion rates at intake for the former two measures were high. However the rates of completion for the measures at discharge and particularly at follow-up were very low. Despite written and telephone reminders requesting patients to complete and return the measures at discharge and four-month follow-up, only a minority did so, and only

about 20% of patients completed the follow-up assessment at four months. These measures have not therefore been subjected to further analysis.

Following Frank,<sup>329</sup> response was defined as a clinically significant reduction in symptoms following the onset of treatment, and remission as the virtual absence of depressive symptoms. In operational terms, “remission” was considered to be a final PHQ score of five or less.<sup>253,263,264</sup> “Response” was defined as either a drop of five or more in PHQ score or a reduction of at least 50% in PHQ score during the course of treatment.<sup>321,322</sup>

Clinical outcomes were analysed by age at referral, gender, and deprivation quintile derived from the Scottish Index of Multiple Deprivation (SIMD).

#### *4.8.2 Measures of prescribing change*

The primary outcome measure for this study was change in the Defined Daily Dose (DDD) of antidepressants prescribed for the catchment population covered by the Doing Well service, compared with local and national controls. A Defined Daily Dose is a theoretical unit of measurement defined by the World Health Organisation as the “assumed average maintenance dose per day for a drug used for its main indication in adults.” This measure and its strengths and weaknesses are described in section 3.3.6.

The Gross Ingredient Cost (GIC) is a standard measure of drug cost, and represents gross ingredient cost to the NHS for an individual drug, before any discount is applied. Alternative measures of drug costs include “Net Ingredient Cost” (the cost of drugs and appliances after deduction of any discount, plus special payments made to dispensing doctors) and Gross Cost (Net Ingredient Cost, plus any additional payments, dispensing fees and allowances

centrally paid). Gross Ingredient Cost was chosen for the pragmatic reason that it is routinely available.<sup>330</sup> Formulary compliance is also reported for the Doing Well practices, being the proportion of all antidepressant defined daily doses accounted for by the formulary drugs fluoxetine, citalopram and lofepramine.

Prescribing information in Scotland is collated and published by the Information and Statistics Division of the Scottish Government, and that data is the source of the prescribing information reported in this study. This information is gathered nationally based on pharmacy returns, and reported at practice level. Data is reported quarterly, and is independent of Doing Well or any local stakeholder.

Routinely-collected prescribing information in Scotland only counts the amount of drug dispensed, but not the dose to be taken or the duration of treatment. The implications of this for the assessment of prescribing change are discussed in section 3.3.6 of the Literature Review.

Scottish data does not allow for a linkage to be made between drug use and the condition for which it was prescribed. For example, it is not possible to know what proportion of amitryptiline use relates to depression and what proportion is prescribed for other indications such as enuresis or neuropathic pain.

The information about antidepressants that is collected by the Information Services Division is based not on prescriptions written, but on drugs dispensed. There is significant, regular variation in the defined daily doses dispensed each month, as discussed in section 3.3.6.2 of the literature review.

For these reasons, analysis of prescribing in this study uses WHO definitions of DDDs, reports prescribing rates by month (adjusted for days in the month), and makes comparisons against equivalent periods year-to-year. The study analyses DDDs per 1,000 population using monthly practice populations for local areas and annual population estimates for comparison with the rest of Scotland. These are the most detailed data available in both instances. Although the evaluation of clinical outcomes represents the first 27 months of the implementation of Doing Well to October 2006, prescribing data is presented to February 2008, since there may be a time lag between the implementation of a new service and a response in terms of prescribing practice.

#### *4.8.3 Comparisons of antidepressant prescribing*

Neighbouring practices (referred to as “non-Doing Well” practices) were part of the Renfrewshire Community Health Partnership. They had access to the same secondary care mental health services, and also were able to attend educational meetings held by Doing Well during which the key messages – only prescribe for more severe depression, and use formulary choices whenever possible – were promoted. Non-Doing Well practices also received some Doing Well-authored promotional and educational material, just as the Doing Well practices did. The main difference between the Doing Well and non-Doing Well groups was therefore in terms of their access to the Doing Well clinical service for people with depression. Unable to use this resource, non-Doing Well practices would instead have used the local community mental health team and psychology resource.

These 16 practices served a population of 101,000 people. All practices in NHS Argyll and Clyde had access to Prescribing Advisors at the time of the study. These were pharmacists

employed by NHS Greater Glasgow and Clyde to review prescribing in the Health Board area and offer feedback and guidance on best practice. These pharmacists operated independently of Doing Well.

The characteristics of the differing groups are set out in Table 4-3.

	Access to full Doing Well clinical intervention	Doing Well promotional/ educational material	Prescribing advisors
Doing Well (Renfrewshire, 76,000 pop)	✓	✓	✓
Doing Well neighbours (Renfrewshire, 101,000 pop)		✓	✓
Inverclyde (~90,000 pop)			✓
Scotland			+/-

**Table 4-3: characteristics of areas used to compare changes in antidepressant prescribing**

Three outcomes were measured:

- change in defined daily doses of antidepressants per 1,000 population
- change in gross ingredient cost
- change in proportion of prescriptions consistent with a three-drug local antidepressant formulary (Renfrewshire/Inverclyde only)

For each of these three parameters, data was averaged for January to June 2004 (the six months before the Doing Well programme was implemented) and for September 2006 to

February 2008 (the most recent data then available). Defined Daily Doses per 1,000 population for each participating and control practice was used to calculate the actual DDDs prescribed for each practice each month. Dispensed Gross Ingredient Cost (GIC) per practice per month was recorded. Since these data sources record all dispensed prescriptions in Scotland, there was no missing data.

#### *4.8.4 Service throughput*

Referral rates from each GP practice, waiting times and duration and number of total contacts were recorded for every patient. The system also collated information about age, gender and postcode. Deprivation was measured by linking each postcode with the deprivation decile or quintile for that data zone according to Information Services Division data.

#### *4.8.5 Statistical Analysis*

Baseline demographic statistics are shown descriptively.

The primary outcome measure was an assessment of change in Defined Daily Doses of antidepressants prescribed by the Doing Well practices compared with other practices in Renfrewshire and Inverclyde, and in Scotland as a whole.

Secondary analyses were conducted to describe the characteristics of the patients using the service, and to assess the clinical outcomes for patients in terms of change in PHQ scores.



Variables were compared between groups with 2-sample t-tests or ANOVA. Within-group differences were compared using paired statistical methods.

Relationships between numerical variables were measured using correlations.  $\chi^2$  was used to test associations between categorical variables. Multiple regression analysis was used to test the effects of several variables on the main outcomes of interest.

All analyses were carried out with Minitab statistical software (version 15.1), using significance levels of five percent.

## 5. Results

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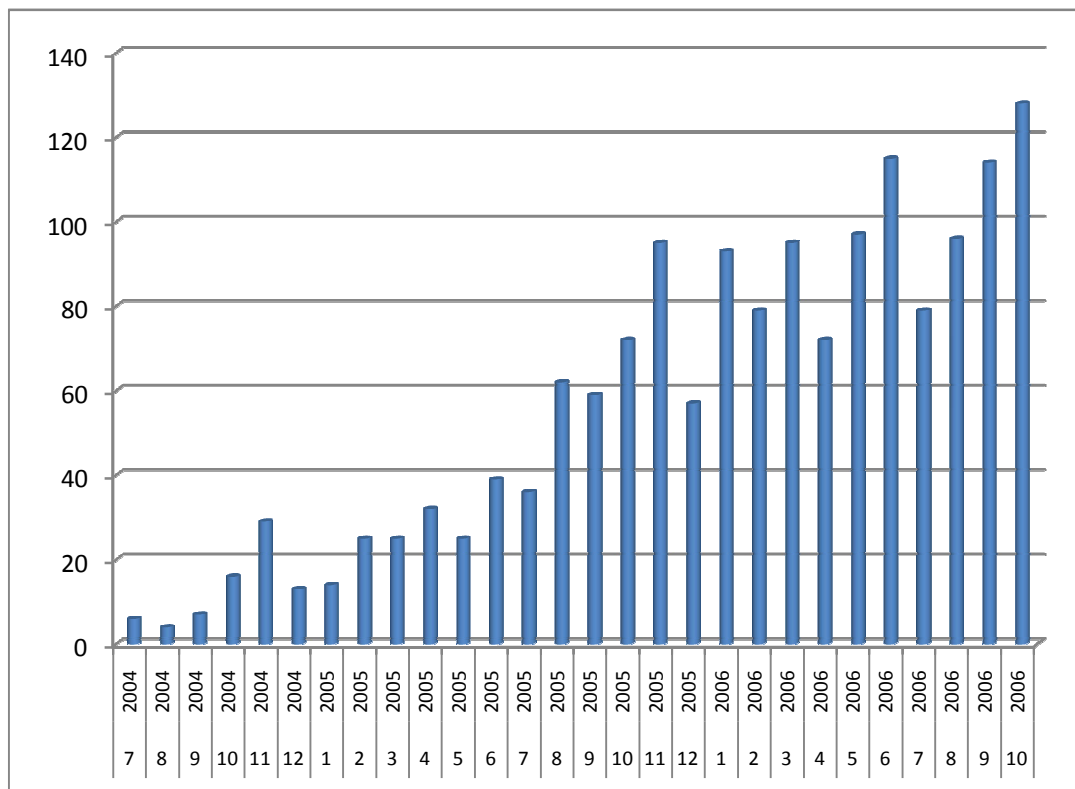
### 5.1 Service use

All patients referred to "Doing Well" during the three-month pilot period (July 04-Oct 04) and all patients referred during the first 24 months of the full programme implementation (Oct 04- Oct 06) are included in the following analysis, with the exception of two patients who declined consent for anonymised information about their care to be used for research purposes.

#### *5.1.1 Referral patterns*

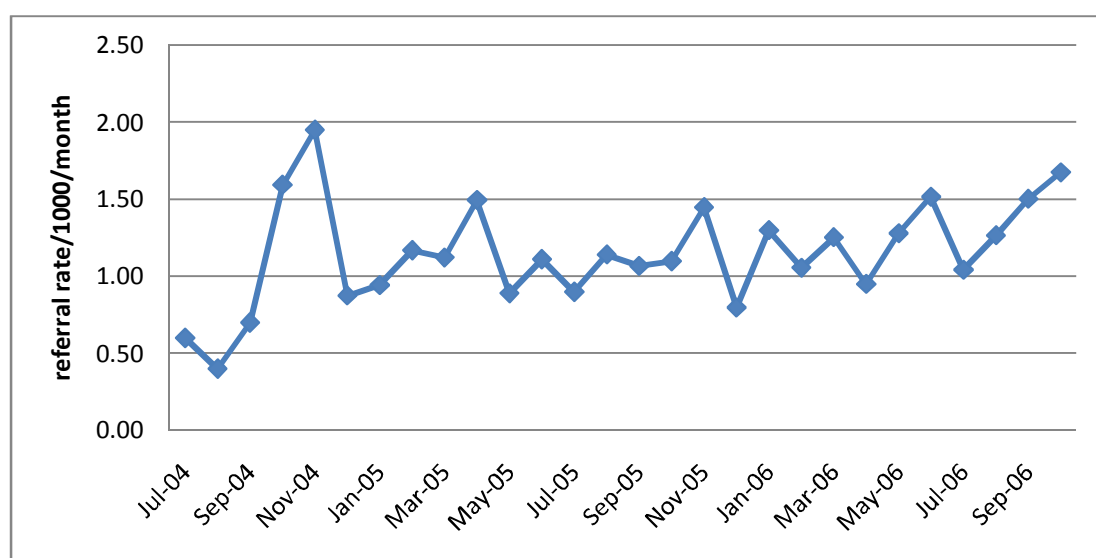
The number of referrals to the service gradually increased each month as more practices joined the programme. The monthly referral rate for all practices is represented in Figure 5-1. It shows, as anticipated, that there was a gradual increase in monthly referrals to the programme which stabilised after February 2006, by which time all practices had been recruited.

The capacity of "Doing Well" to cope with new referrals had been estimated to be about 100 new referrals per month. The average referral rate from March 2006 after full recruitment of practices was 99.5 referrals per month.



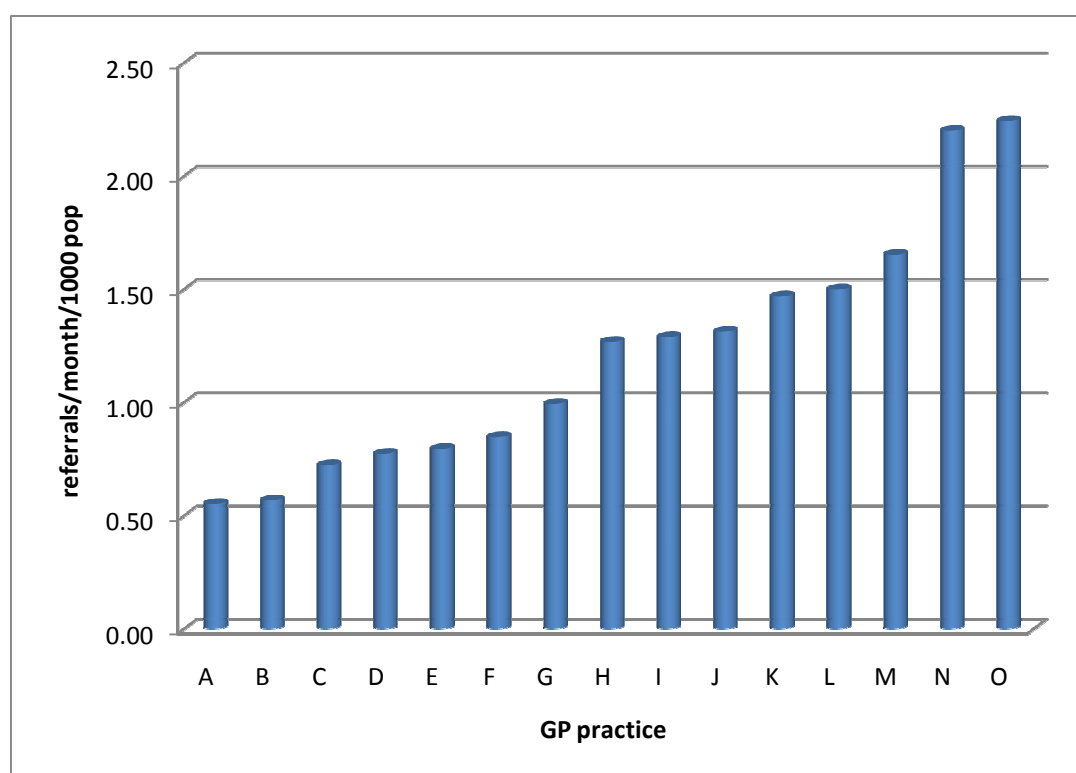
**Figure 5-1: number of referrals by month**

However, after the “pilot” period ended in October 2004, monthly referrals remained broadly stable, averaging 1.20 referrals/month/1,000 population (Figure 5-2).



**Figure 5-2: Referral rate per month per 1,000 catchment population**

As Figure 5-3 shows, there was substantial variation in referral rates between practices, with a range between 0.77 referrals per month per thousand population and 2.24 referrals per month per thousand population.

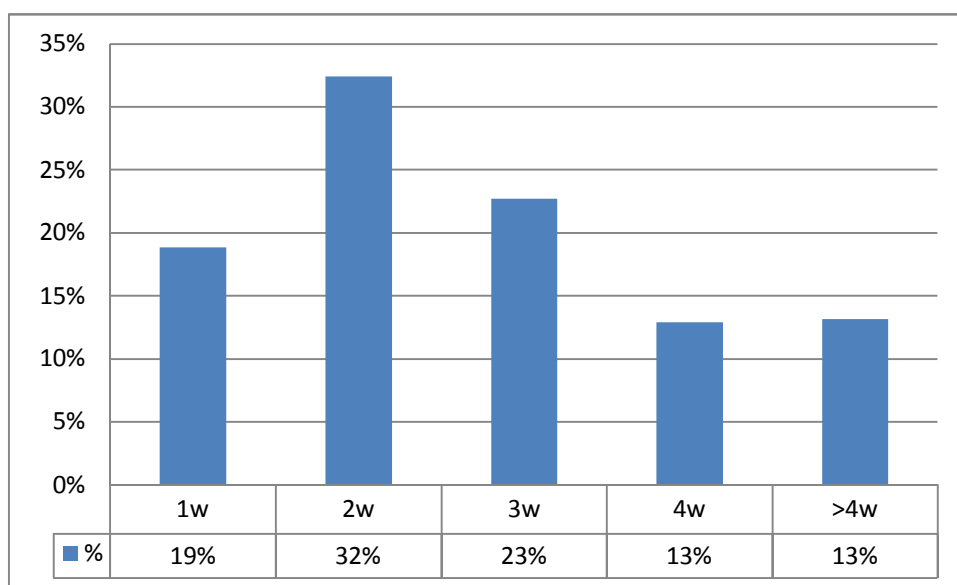


**Figure 5-3: Referral rate per month per 1,000 practice population by practice**

In other words, even after adjustment for list size and date of joining, some practices still referred three times more than others. Regression analysis did not show any association between the referral rate and the mean deprivation decile (regression coefficient -0.11;  $p=0.215$ ) or mean PHQ at referral (regression coefficient 0.09;  $p=0.167$ ). The observed variation in referrals must therefore relate to other factors, including individual practitioner behaviour.

### 5.1.2 *Waiting times*

The mean waiting time between referral and first appointment was 17 days, and the median wait 15 days as shown in Figure 5-4. One thousand and eleven out of 1165 patients (87 %) were seen within 4 weeks of referral. Longer waiting times often resulted from patient requests, or reflected reduced staffing because of absence or annual leave.



**Figure 5-4: Duration of patient waiting times by week**

### 5.1.3 *Flow of patients through the service*

Patients were grouped into the following “outcome categories” for further analysis (Table 5-1).

Category	Definition
Inappropriate referral	Did not meet inclusion criteria for participation
Did not attend	People offered an appointment but who then: declined referral to service, or did not attend any appointment offered, or did not "opt-in" to revised appointment system introduced in August 2006
Transfer of care	Required input from other services and discharged to their care
Disengaged	Dropped out of treatment after at least one contact and did not respond to further invite to re-engage
Treatment complete	All care and assessments carried out in keeping with protocol

**Table 5-1: definition of outcome categories**

A total of 1,584 patients were referred during the study period. Eighty-one patients referred (5%) did not meet inclusion criteria and are not included in further analysis. This group included 28 people aged over 65 years. Two further patients were excluded from analysis at their request. The experience of the programme was that the proportion of inappropriate referrals was highest within the first few weeks of practice recruitment, and diminished thereafter in response to feedback from "Doing Well" clinicians.

Of 1,501 patients eligible for inclusion in the study, 294 (20%) did not attend any appointment offered. Thirty-eight people (3% of those eligible) declined the offer of an appointment. Therefore 332 (22%) people were appropriately referred but dropped out of the programme before assessment.

Of this 1,501 people eligible to join the study, 1169 (78%) attended at least one appointment. Six hundred and fifty-four people (44% of eligible patients) completed treatment in accordance with the protocol.

Three hundred and twenty people (21%) “disengaged” from treatment after being seen at least once. This group includes one patient who died and ten who moved away, as well as those who chose not to maintain contact with the service. The one death known to the service was the result of suicide. An internal review was conducted of this suicide and did not find any deficiencies in care provided by the Doing Well team. The “disengaged” group includes people who did not respond to treatment as well as people who had been showing signs of clinical improvement.

One hundred and ninety-five of the 1501 eligible patients (13%) were transferred to other services for ongoing care.

In total therefore, 849 patients (57%) either completed treatment or had their care transferred to more appropriate services. 652 patients (43%) either did not attend for treatment or dropped out of care before the planned treatment had been completed.

The flow chart in Figure 5-5 outlines the numbers of patients falling into the “outcome categories” described above.

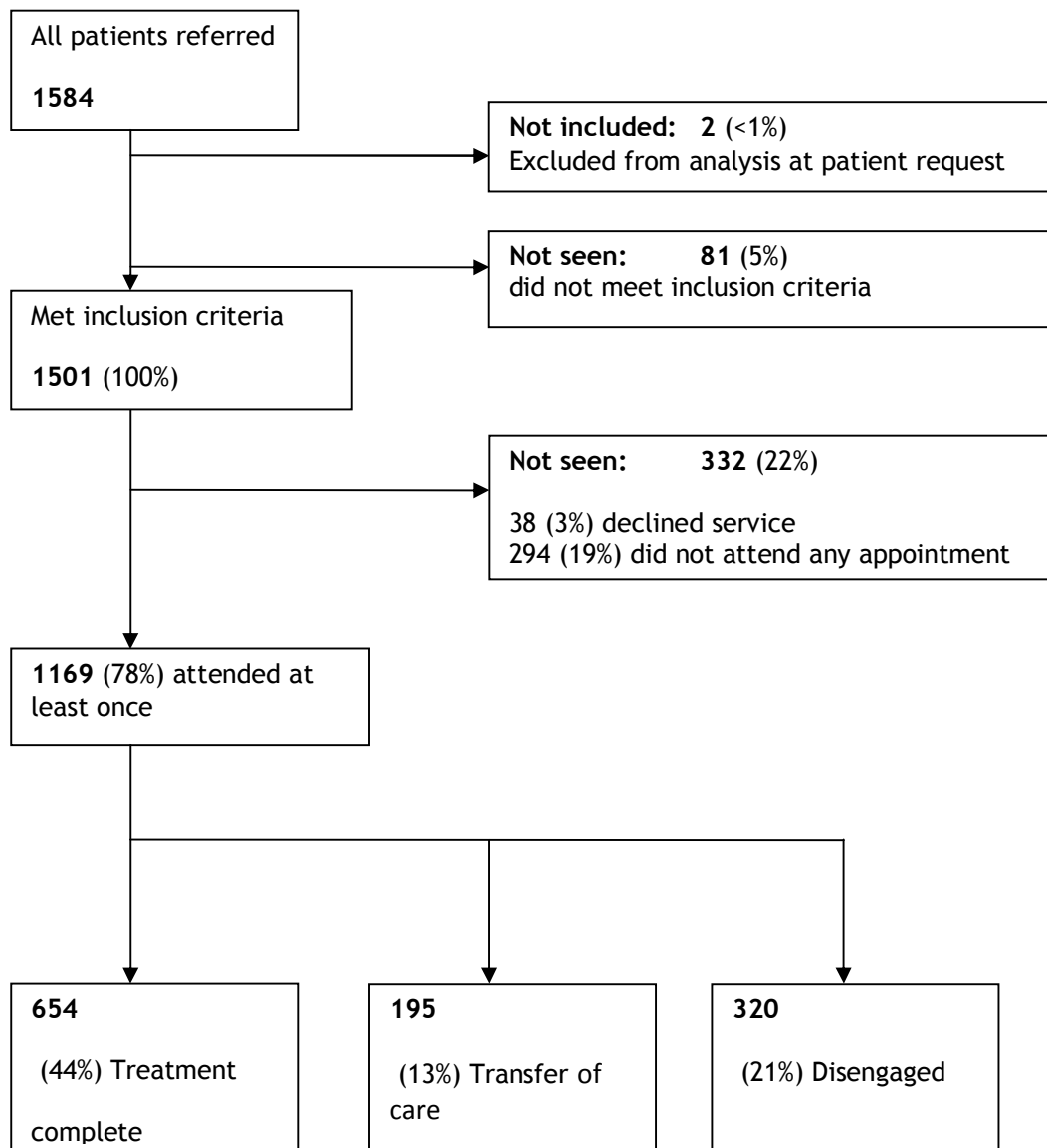


Figure 5-5: Flow chart of subjects referred to programme July 04- October 06



### 5.1.4 Demographic characteristics of people referred

The demographic characteristics of all patients who met inclusion criteria are summarised in Table 5-2. Comparisons between groups for these parameters are made in the following subsections.

Outcome category	Mean age (standard deviation)	percentage female	Mean deprivation decile 1-10 (standard deviation)	Mean PHQ score at referral (standard deviation)
All (n=1,501)	37.46 (12.19)	67%	5.21 (3.01)	17.05 (5.20)
Did Not Attend (n=332)	33.05 (11.78)	66%	4.55 (2.82)	17.12 (5.50)
Disengaged (n=320)	35.25 (11.48)	68%	4.86 (2.96)	17.33 (5.01)
Transfer of care (n=195)	38.83 (11.87)	65%	4.94 (2.98)	17.54 (5.55)
Treatment complete (n=654)	40.38 (11.98)	68%	5.79 (3.02)	16.73 (5.01)

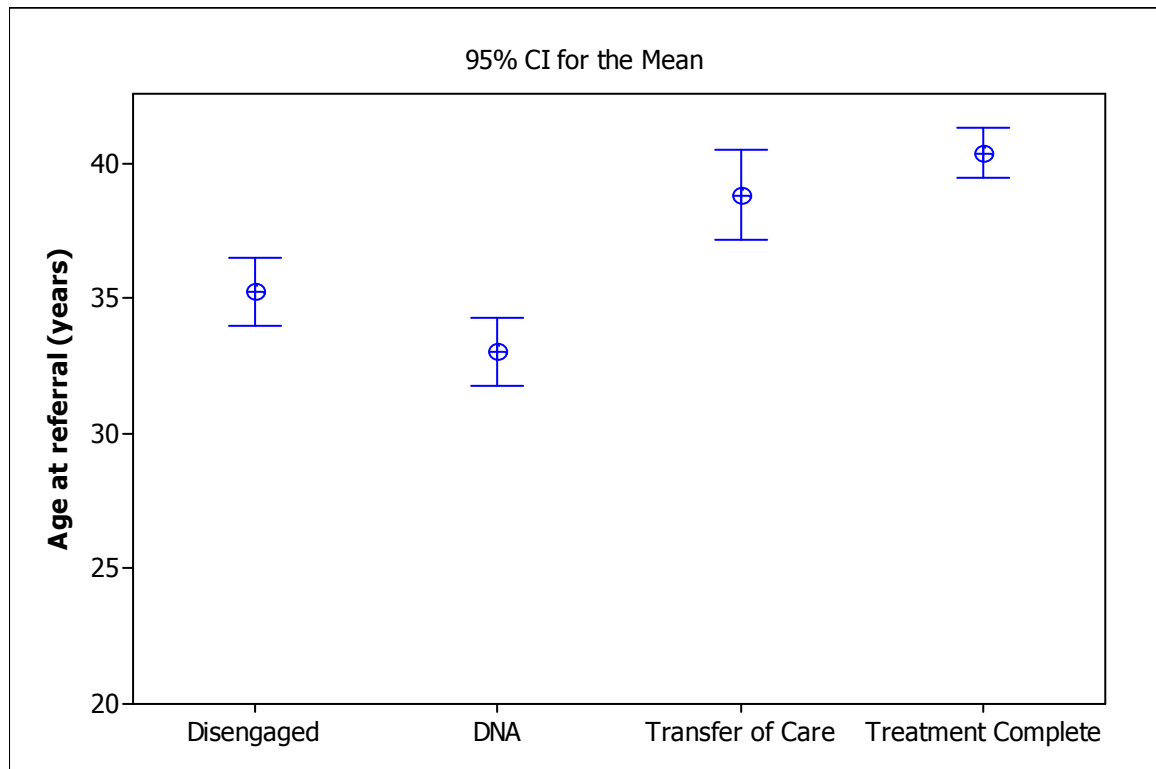
**Table 5-2: demographic characteristics of patients referred, shown for all referrals and for outcome categories.**

#### 5.1.4.1 Age & Gender

Sixty-eight percent of people referred to the programme were female, as shown in Table 5-2. The gender ratio in the outcome categories varied slightly, but was not statistically significant ( $\chi^2$  test).

The mean age of patients referred to the service was 37.5 years. Between-group differences were examined using one-way ANOVA, which showed that the “disengaged” and “did not

attend” groups were significantly younger than the “treatment complete groups” ( $p<0.001$  for both); there was no significant difference in age between the “treatment complete” and “transfer” groups ( $p=0.442$ ). Mean ages for the different outcome categories are shown in Figure 5-6.

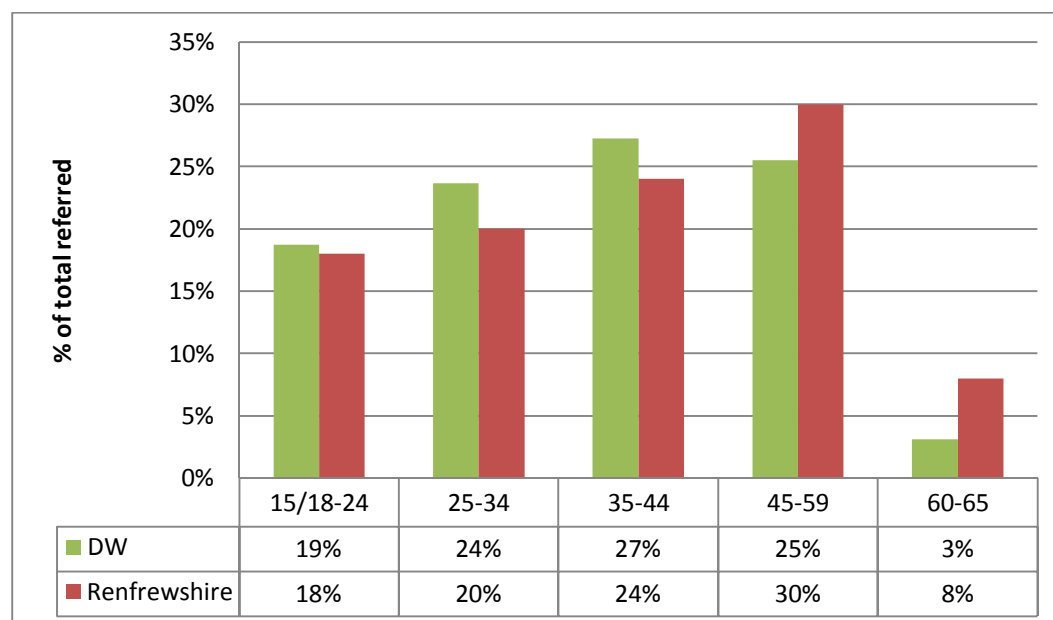


**5-6: age at referral for different outcome categories showing 95% confidence intervals.**

**Note y axis does not start at zero.**

The chart in Figure 5-7 shows the proportion of Doing Well referrals in different age categories, compared with the proportion of the Renfrewshire population in those categories.<sup>331</sup> Note that census data for the Renfrewshire area is only available for the 15-24 age category,<sup>331</sup> although Doing Well only received referrals for people aged 18 or more. Nonetheless, the data shows that Doing Well received a greater proportion of referrals for people aged less than 45 years than would be expected in the general population. Seventy

percent of eligible Doing Well referrals were for people aged under 45 years, although this group represent only 62% of the general population.

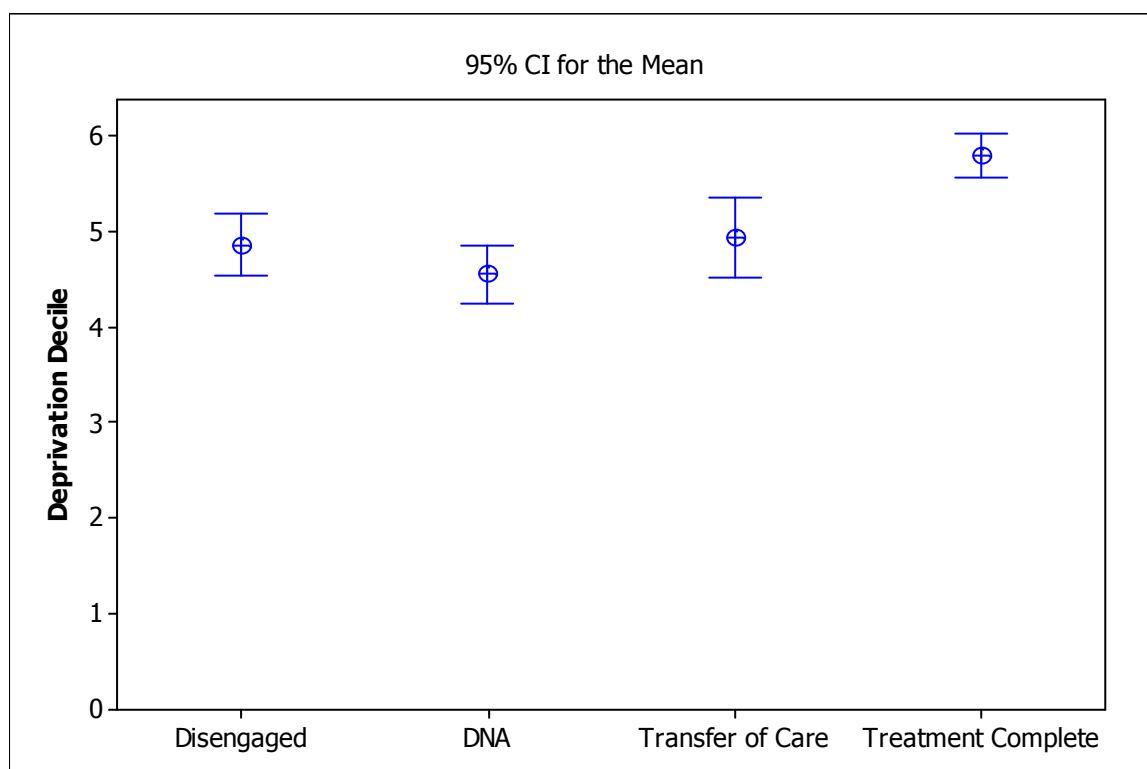


**Figure 5-7: histogram of referrals by age group to Doing Well (DW) compared with equivalent age categories in the Renfrewshire population. Note that the “15/18-24” age group shows the proportion of people in Renfrewshire aged 15-24, but Doing Well referrals were aged 18-24.**

#### 5.1.4.2 Deprivation

Referrals were received from patients living in postcodes in all deprivation quintiles.

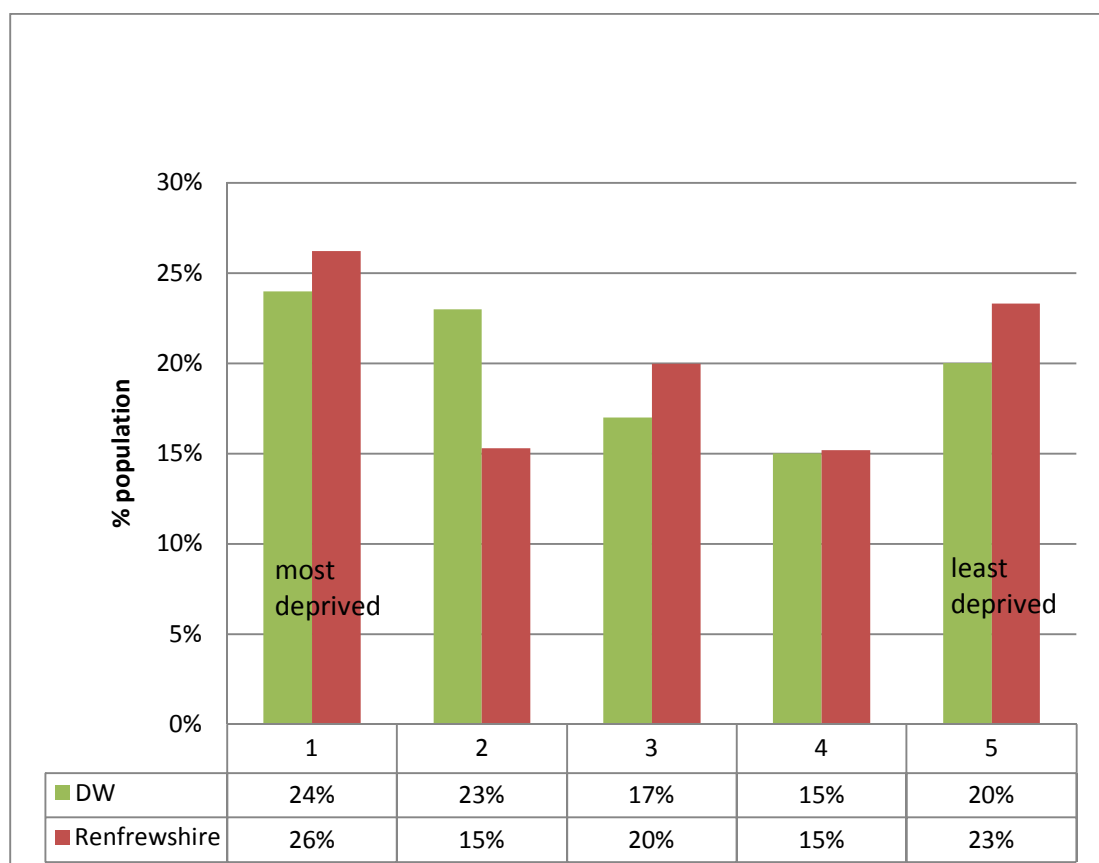
Analysis of variance was used to test for differences between the outcome categories in relation to deprivation scores, and the “treatment complete” group were found to be significantly less deprived than any other category ( $p < 0.001$  for disengaged and DNA groups,  $p = 0.004$  for “transfer of care” group). Mean deprivation deciles for each of the outcome categories are shown in Figure 5-8.



**Figure 5-8: mean deprivation decile for patients in each outcome category**

These figures are compared with population data for Renfrewshire as a whole in Figure 5-9, which shows the proportion of the Renfrewshire population living in each deprivation quintile, and the proportion of Doing Well referrals received from that quintile.

There were slightly more referrals to Doing Well from the two most deprived quintiles (47%) than would have been expected from the proportion of the population living in those areas (41%). Conversely, there were slightly fewer referrals from the most affluent quintiles (35%), although 38% of the population live in those areas.



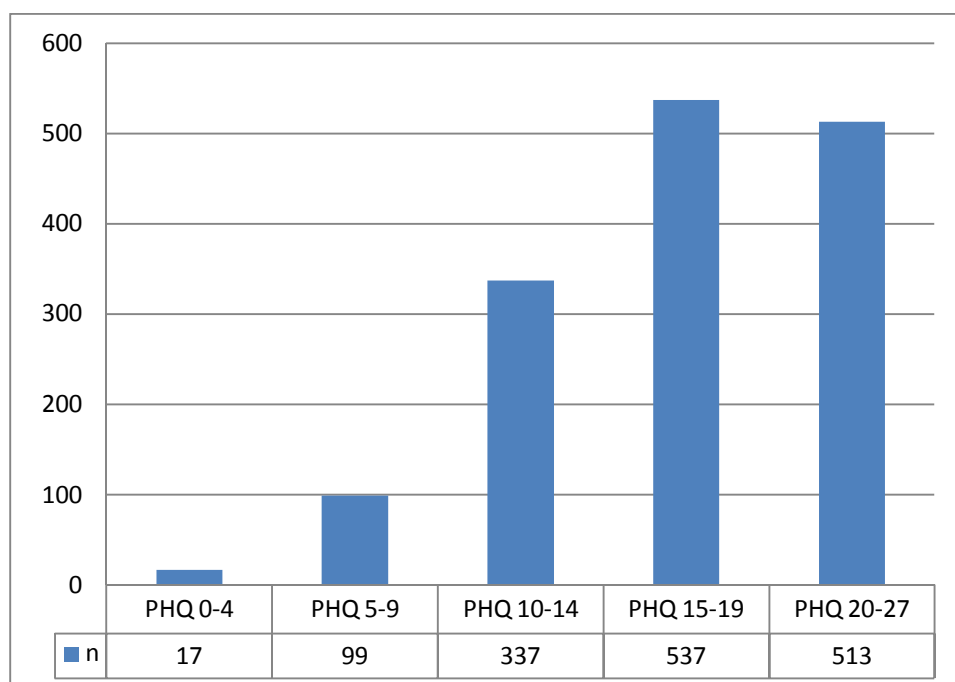
**Figure 5-9: Renfrewshire population and referrals by deprivation quintile**

#### 5.1.4.3 Ethnicity

Information about ethnicity was not routinely collected as part of this study.

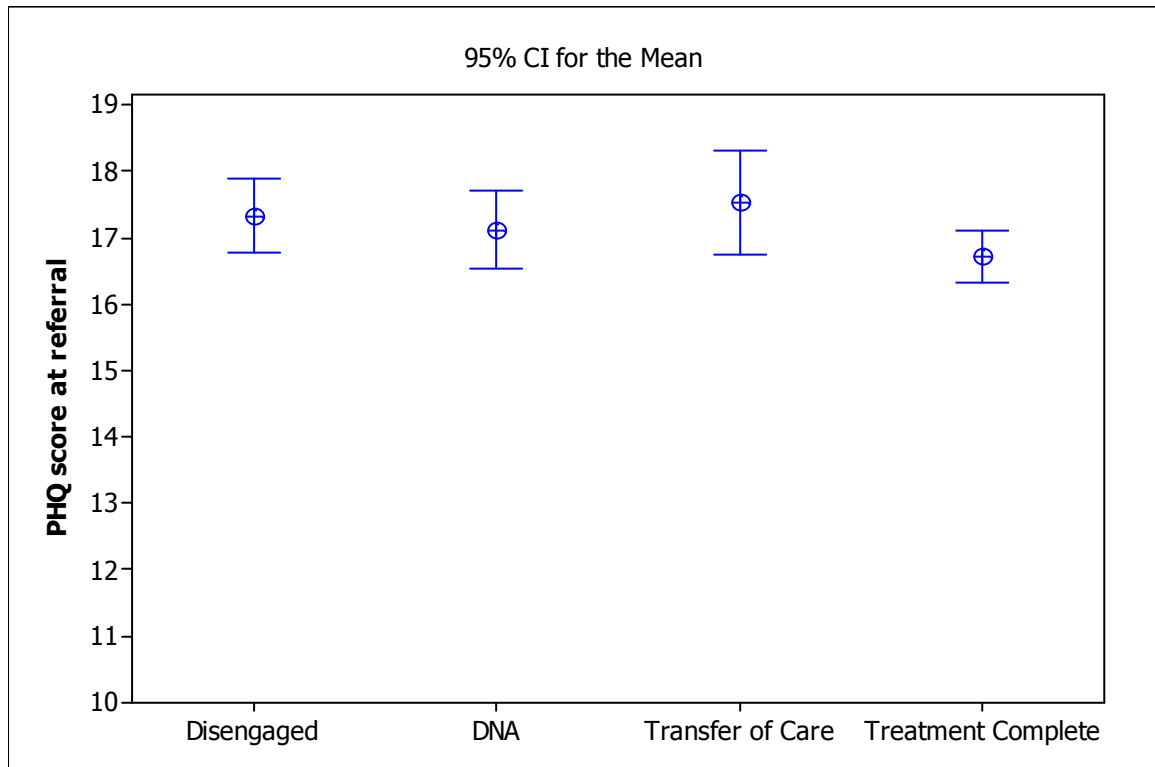
#### 5.1.4.4 Depression severity at referral

Overall, 453 (30%) of the 1501 referrals had mild to moderate depression (PHQ<15 at referral), and 1050 (70%) of patients had moderately severe to severe clinical depression (PHQ=>15 at referral), as shown in Figure 5-10.



**Figure 5-10: number of referrals by PHQ category at referral**

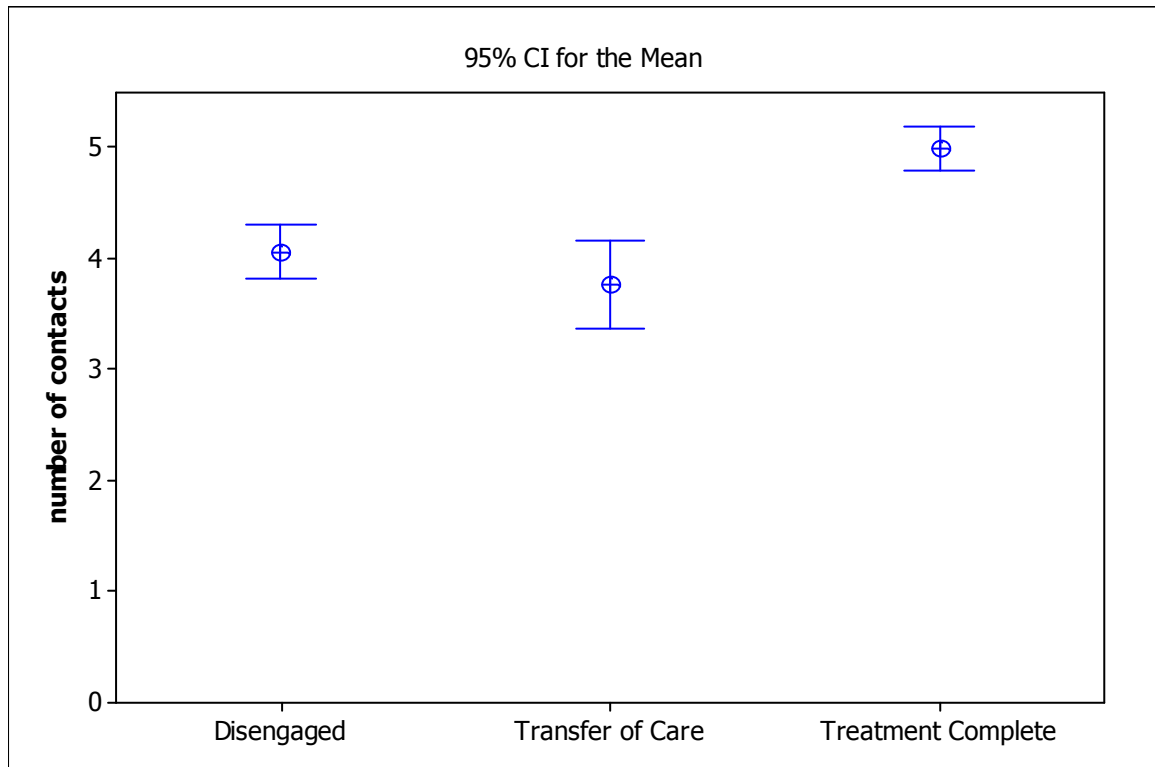
The mean PHQ score at referral for women was 17.3 and was 16.6 for men, a statistically significant finding ( $p=0.041$ , 95% confidence interval for difference 0.025- 1.280). There was no significant difference in depression severity at referral (as measured by average PHQ) between people in the different outcome categories (Figure 5-11).



**Figure 5-11: mean PHQ score at referral for outcome categories. Note y axis does not start at zero.**

### *5.1.5 Number of contacts and duration of treatment*

The mean number of clinical contacts for subjects in different outcome categories who attended at least one appointment is shown in Figure 5-12. Patients completing treatment had an average of 5.0 contacts, and those disengaging from treatment had 4.1. The fewest contacts (3.8) were seen in the “transfer” group who continued treatment in other settings. Both the “disengaged” and “transfer of care” group were significantly different from the “treatment complete” group ( $p < 0.001$  for both), but the “disengaged” and “transfer of care” groups were not significantly different from each other ( $p = 0.203$ ).

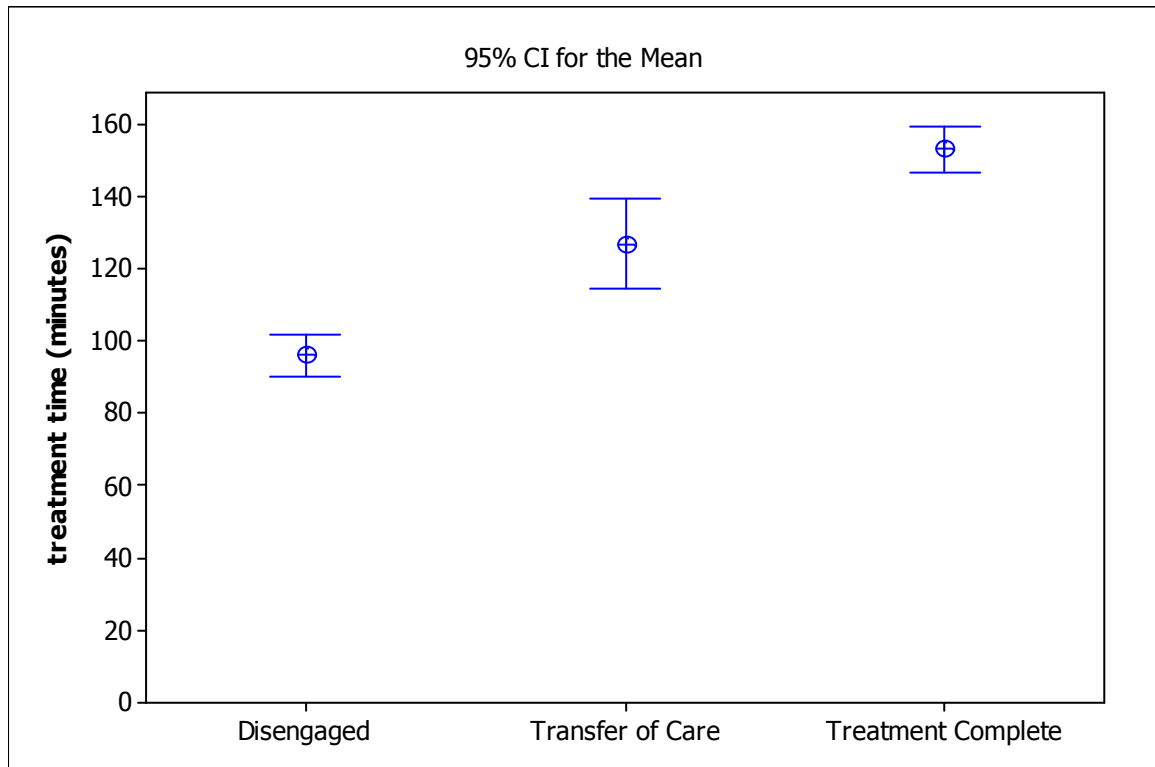


**Figure 5-12: mean number of clinical contacts by discharge category**

“Treatment time” was recorded as the time spent in personal contact with a patient, which was principally accounted for by face-to-face meetings, but also included some telephone and email contact. Administrative time (writing letters or completing paperwork) was not included in “treatment time”. There were significant differences in total treatment time between groups.

Figure 5-13 shows the mean duration of treatment time by outcome category. Mean contact time was 151 minutes for patients completing treatment (median 135 minutes), 95 minutes for the “disengaged” group (median 80 minutes) and 125 minutes for the “transfer” group (median 100 minutes).

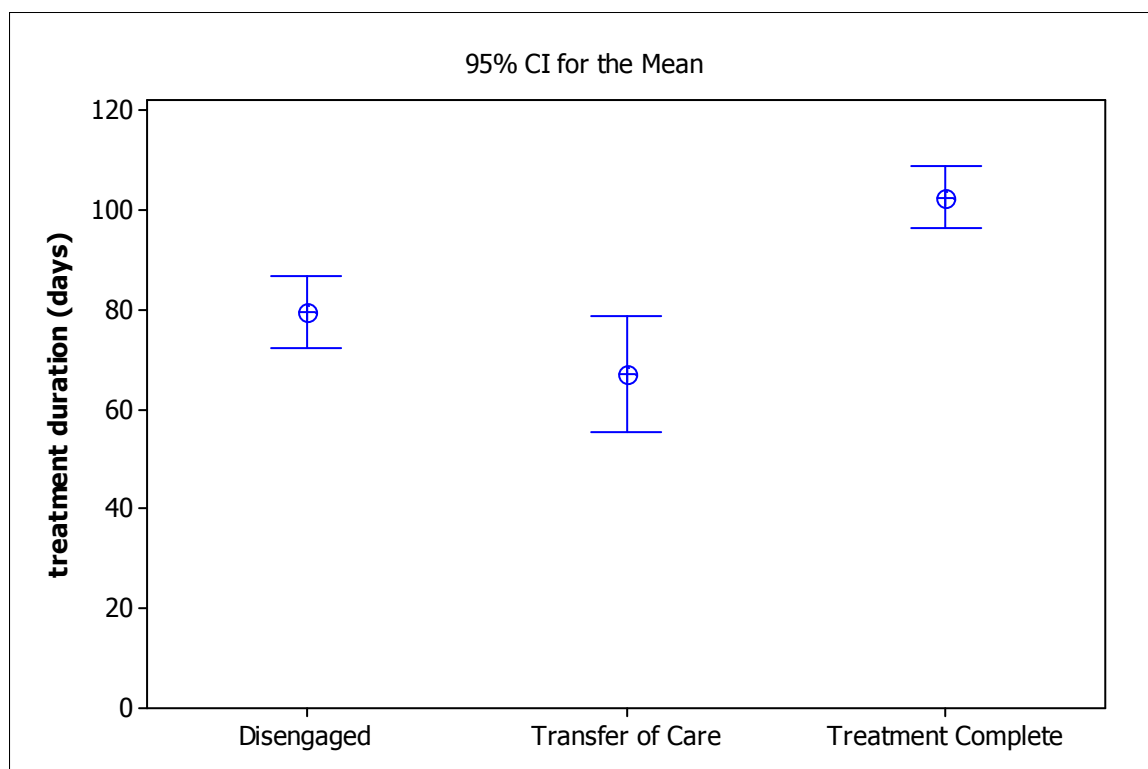




**Figure 5-13: mean duration of treatment time by outcome category**

When the three groups were compared using one-way ANOVA, the differences between the treatment “complete”, “transfer” and “disengaged” groups were all statistically significant ( $p < 0.001$ ).

Figure 5-14 shows that the “treatment complete” group spent an average of 102.5 days in treatment. The corresponding time in treatment was 79.5 days for the “disengaged” group and 67.1 days for the “transfer” group. Analysis using one-way ANOVA showed that there was no significant difference between the “disengaged” and “transfer of care” groups ( $p = 0.238$ ), but that the “treatment complete” group was different from both the “disengaged” and “transfer of care” groups ( $p < 0.001$  for both).



**Figure 5-14: mean duration of treatment in days from first to last appointment**

### *5.1.6 Characteristics of “Did Not Attend” group*

The following figures compare the characteristics of the “Did Not Attend” group with people who attended at least once (“treatment complete”, “transfer” and “disengaged” groups).

The 332 people in the “Did Not Attend” group were significantly more likely to be younger than the 1169 patients who attended for treatment (mean difference -5.6 years,  $p < 0.001$ ) and more likely to come from a more deprived area (mean deprivation quintile -0.04,  $p < 0.001$ ).

There was a slightly higher proportion of men (34.2%) in the “Did Not Attend” group compared to those who were seen (33.3%), but this was not statistically significant ( $\chi^2$  test,  $p>0.1$ ). However, there was a significant difference in the mean wait to be seen, with those who did attend for treatment having a slightly shorter waiting time (Table 5-3;  $p<0.001$ ).

Wait time to first appointment	Mean	95% CI
DNA	19.1	17.8- 20.5
Seen	17.0	16.3-17.6

**Table 5-3: wait time to first appointment for “Did Not Attend” group**

## 5.2 Clinical outcomes

### 5.2.1 *Change in PHQ by outcome category*

The primary clinical outcome measure was depression severity as measured by the Personal Health Questionnaire (PHQ). The change in PHQ score was derived by subtracting the last available score recorded by the "Doing Well" team from the score recorded by the GP at referral.

A decision was made not to include the "did not attend" (DNA) group in analysis of outcomes because the only PHQ score available for this group was that recorded by their GP at referral. This group did not receive any further treatment or have any other PHQ scores recorded.

A conservative analysis might consider the DNA group part of the "intention to treat" cohort, and carry forward this referral PHQ to represent the "final" observation as if treatment had been completed. However including the DNA group in this analysis would bias the outcomes, particularly as the drop-out mechanism was non-random (since younger patients, males and people living in deprived areas were more likely to drop out than others).<sup>332</sup>

For the treatment complete groups the last available score was the PHQ recorded on discharge. For the disengaged and transfer groups, the PHQ was the "last observation carried forward" from the final contact. Since a low initial PHQ score has less scope for absolute change than higher scores, percentage change in PHQ score was also used to describe clinical change.

The analysis of change in PHQ will be done two ways. The following measures will be reported for the whole cohort:

- the mean change in PHQ from referral to last available score
- the percentage change in PHQ from referral to last available score
- the proportion of patients showing a reduction of 50% or more in their PHQ (“clinically significant” change)

Patients referred to Doing Well with a PHQ score of ten or more (indicating depression of at least “moderate” severity<sup>253</sup>) were included in a subgroup analysis of the following measures:

- the proportion of patients showing a drop of PHQ of 5 points or more (“clinically significant” change)
- the proportion of patients showing a reduction in PHQ to 5 points or less (“recovery”)
- The proportion of patients showing a reduction in PHQ to 10 points or less (“remission”)

Analysis was conducted in this way because it would not be clinically or arithmetically appropriate to attempt to calculate PHQ change of five or more points in patients who may have scored below that level on referral. Similarly, anyone referred with a PHQ below ten would be considered to be “in remission” before treatment had begun.

#### **5.2.1.1 Mean change in PHQ**

The mean change in PHQ for each outcome category is shown in Table 5-4. Analysis of the change in mean PHQ before and after treatment using paired samples t-tests is significant for the total cohort ( $p < 0.001$ ), and individually for the transfer group ( $p < 0.01$ ), disengaged and treatment complete groups ( $p < 0.001$ ).

	Mean Difference	t	df	significance	95% Confidence Interval
All	5.08	27.65	1497	< 0.001	4.72- 5.44
Treatment Complete	10.60	44.80	653	< 0.001	10.14-11.07
Disengaged	1.37	4.76	314	< 0.001	0.80- 1.94
Transfer of Care	1.26	2.73	189	.007	0.35- 2.18

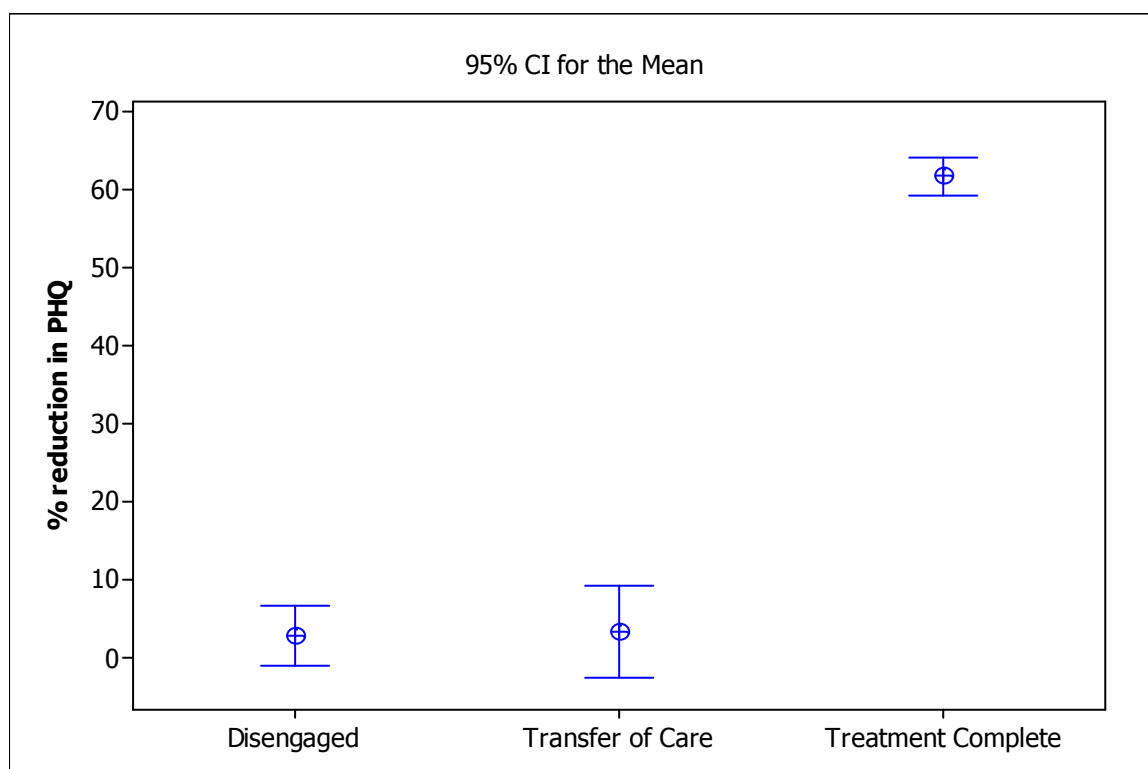
**Table 5-4: change in PHQ from referral to last available score by outcome category**

Although statistically significant, the small changes in PHQ noted in the disengaged and transfer groups (drops of 1.37 and 1.26 PHQ points respectively) do not represent a clinically meaningful change. The mean drop of 10.6 PHQ points in the treatment complete group is both statistically significant and clinically meaningful.

#### **5.2.1.2 Percentage change in PHQ**

Figure 5-15 shows the percentage change in PHQ from assessment (change in PHQ score/PHQ at referral) over the course of treatment. PHQ changed by only 3% in the disengaged and transfer of care groups, but there was a 61.8% reduction in PHQ score for the treatment complete cohort.

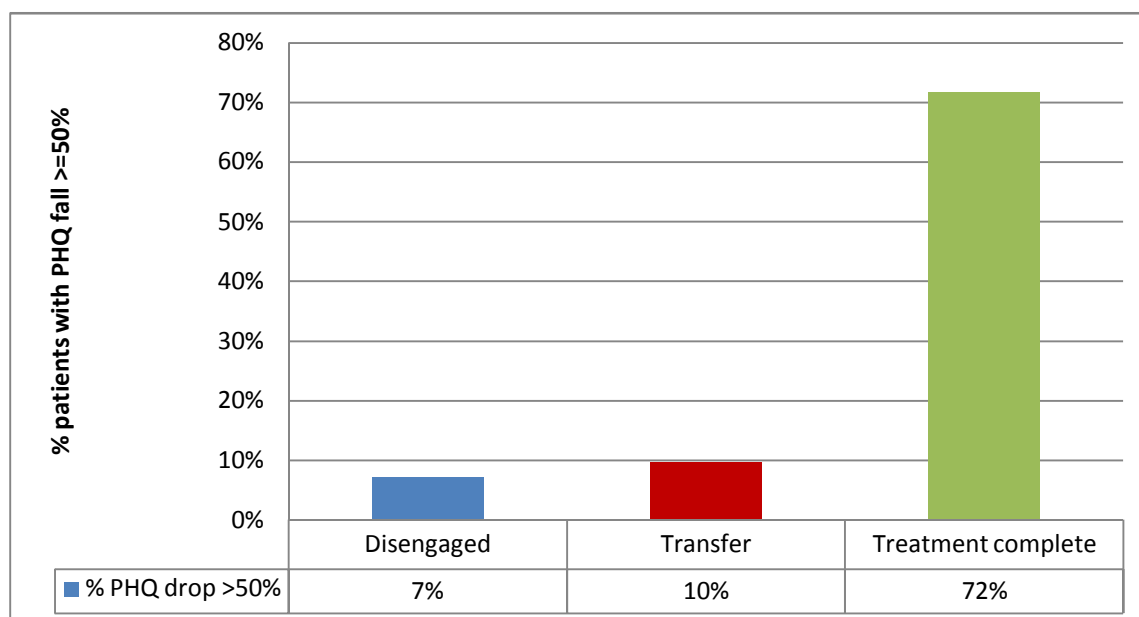
Oneway ANOVA showed significant differences between the outcome categories in relation to percentage change in PHQ. The treatment complete group was significantly different from both the transfer of care and disengaged groups ( $p < 0.001$ ), but the transfer and disengaged groups were not significantly different from one another ( $p = 0.99$ ).



**Figure 5-15: mean percentage change in PHQ from assessment to last observation for disengaged (n=320), transfer (n=195) and treatment complete (n=654) groups**

### 5.2.1.3 Proportion of patients showing improvement of 50% or more

Figure 5-16 shows the proportion of patients in each discharge category showing an improvement in PHQ of 50% or more. The difference in outcomes for the “treatment complete” cohort was statistically significant when compared with people in the “disengaged” and “transfer” categories (n=1157,  $\chi^2=504$ ,  $p<0.001$ ).



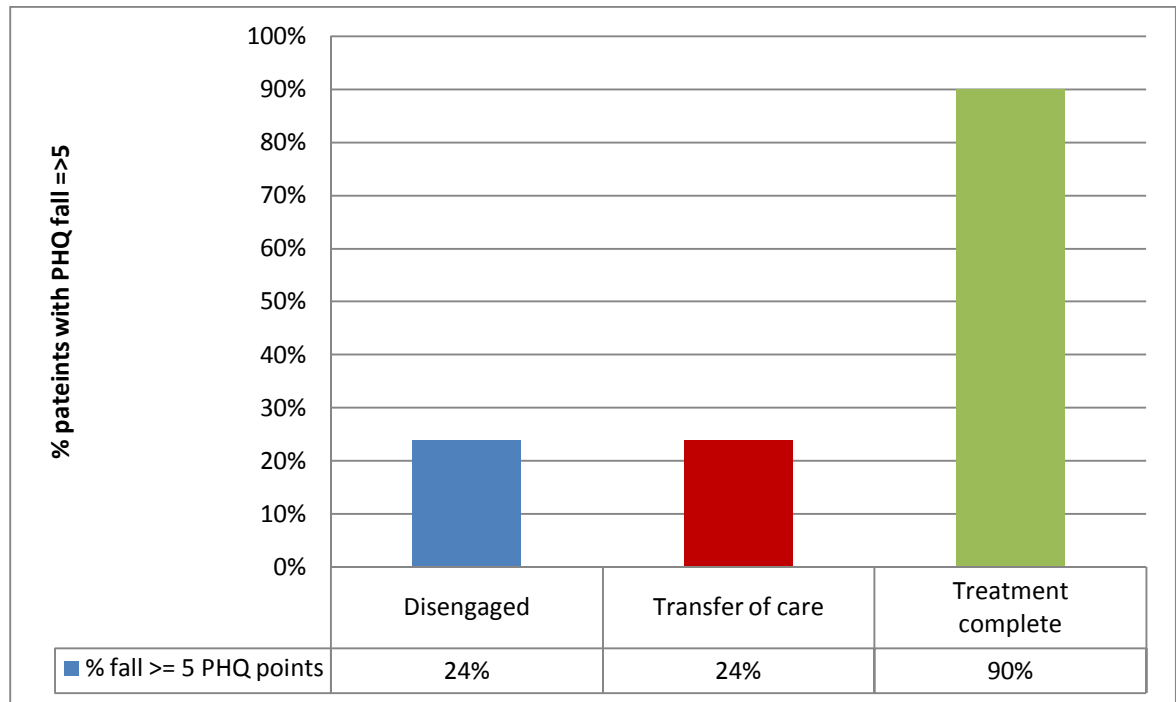
**Figure 5-16: percentage of patients with a PHQ fall or 50% or greater by discharge category**

#### 5.2.1.4 Proportion of patients improving by five or more PHQ points

A drop of 5 points or more was considered a clinically significant change in depression status.<sup>263</sup> The following analysis was conducted on the 1,082 patients who were referred with a PHQ of ten or more.

Figure 5-17 shows that 90% of the treatment complete group (n=602), 30% of the disengaged group (n=300) and 26% of the transfer group (n=180) achieved a “clinically significant” change in their depression status by the end of their engagement with Doing Well by this definition. Comparing patients in the “treatment complete” group with “disengaged” and “transfer of care” groups showed a statistically significant difference in the frequency of patients showing clinically significant change ( $\chi^2 = 371.644$ ,  $DF = 2$ ,  $p < 0.001$ ).





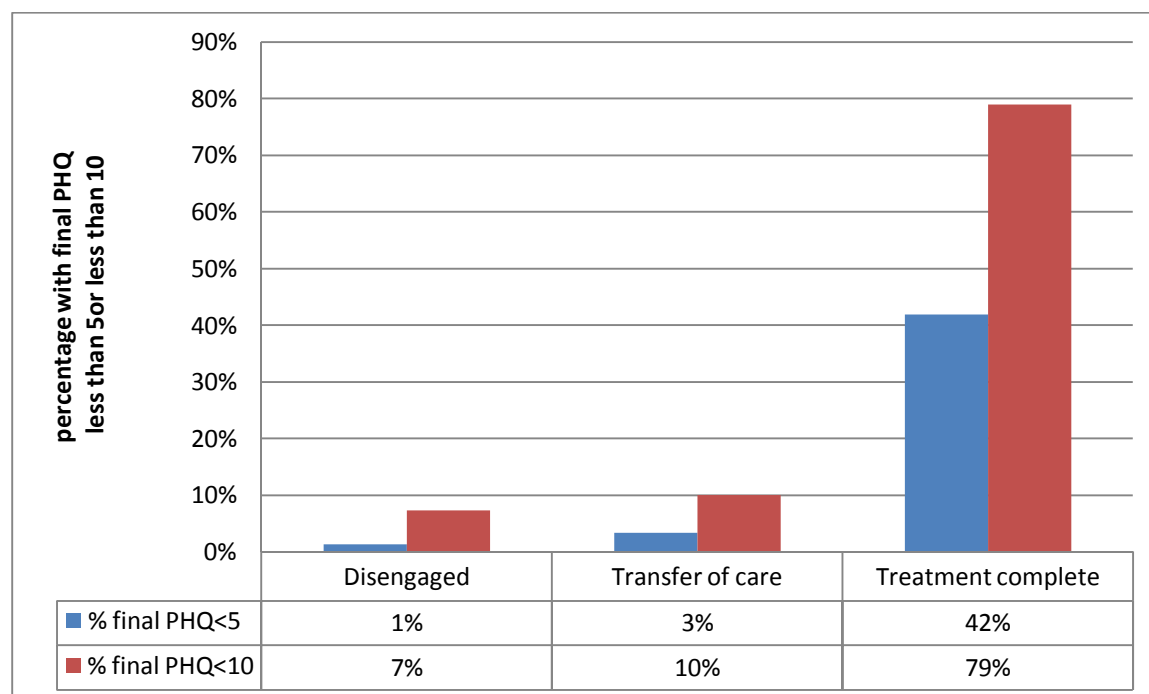
**Figure 5-17: percentage of patients with a PHQ fall greater or equal to 5 by discharge category (initial PHQ  $\geq 10$ ; n=1082)**

#### 5.2.1.5 Recovery or partial remission

A final PHQ score of less than five was considered to be “remission”,<sup>253</sup> and a PHQ score of less than ten was considered to represent partial recovery. Since such terminology is only appropriate for clinical cases, the following analysis was conducted for the 1,082 people referred to Doing Well with a PHQ score of 10 or over in the “treatment complete” (n=602), “transfer of care” (n=180) and “disengaged” (n=300) groups. Figure 5-18 shows that the proportion of patients referred with a PHQ score of ten or more who left treatment with a PHQ of less than five was 42% in the treatment complete group, and 1% and 3% in the disengaged and transfer of care groups respectively. Seventy-nine percent of people in the treatment complete group had a PHQ score between of less than ten at the end of

treatment, compared with 7% in the “disengaged” and 10% in the “transfer of care” groups.

These changes are statistically significant ( $\chi^2 = 248.471$ ,  $DF = 2$ ,  $p < 0.001$ )



**Figure 5-18: proportion of patients with a final PHQ of less than 5 ("remission") or less than 10 ("partial recovery") categories (initial PHQ  $\geq 10$ ;  $n=1082$ )**

## 5.2.2 Factors associated with PHQ change

### 5.2.2.1 Gender

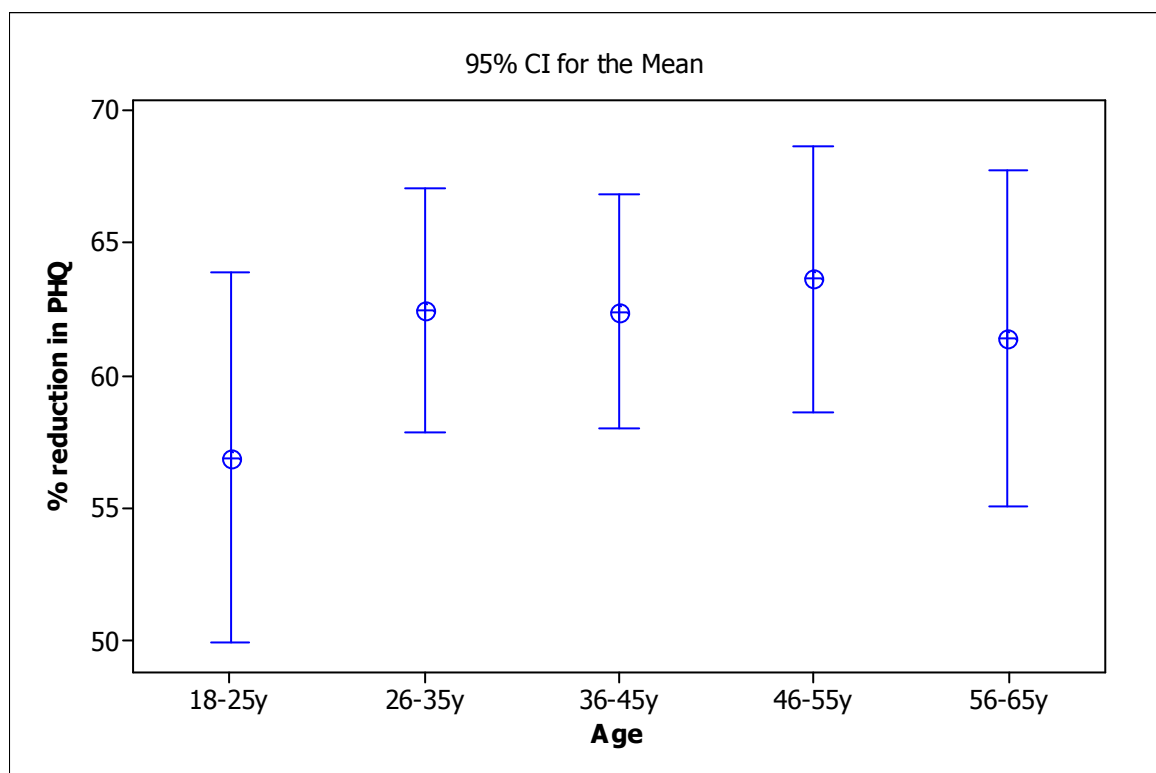
There was a significant effect of gender on PHQ outcomes, with women (who had a slightly higher PHQ score at referral) showing an average PHQ improvement of 1.36 points greater than men in all the groups ( $p=0.006$ , 95% confidence intervals 0.40- 2.33).

### 5.2.2.2 Age

A normal linear regression model was used to examine the association between the age of subjects and change in PHQ by the end of engagement with treatment.

There was no statistically significant association between age and PHQ change at endpoint for any group (disengaged  $p=0.16$ ; transfer of care  $p=0.51$ ; treatment complete  $p=0.70$ ).

These results are shown in Figure 5-19 for the treatment complete group only.

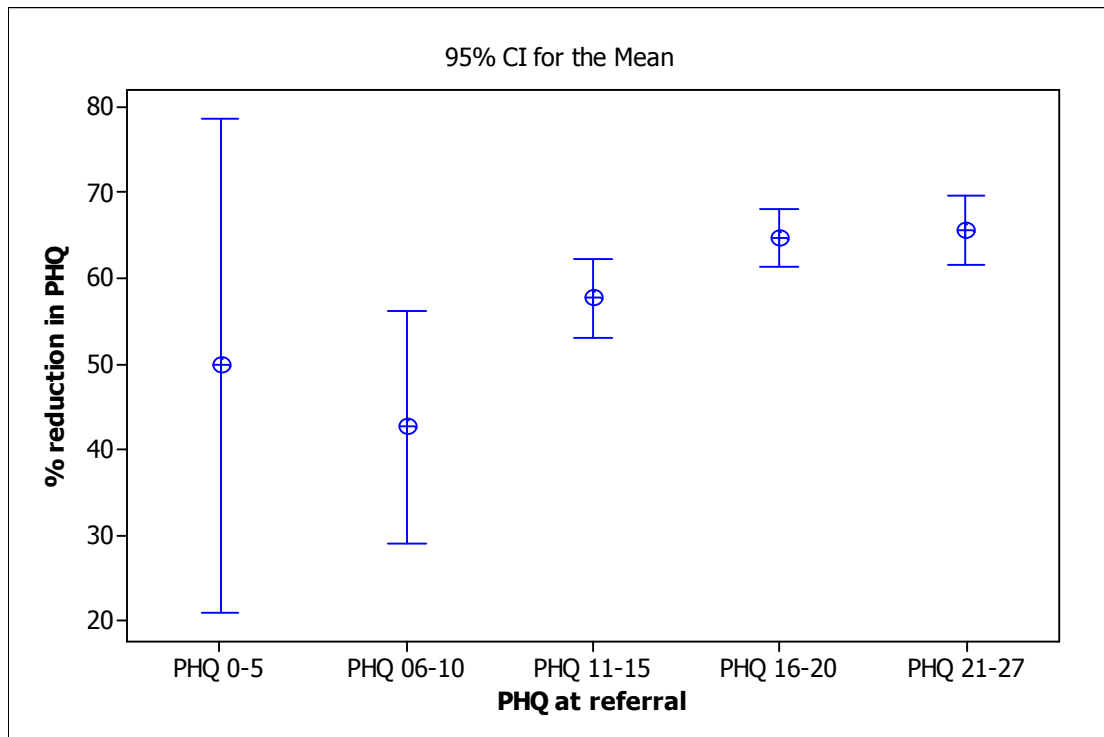


5-19: interval plot showing means (circles) and 95% confidence intervals (bars) for the mean for the relationship between age and PHQ change (treatment complete group only shown here).

### 5.2.2.3 PHQ at referral

There was a clear positive association between the severity of the PHQ score at referral and the absolute reduction in PHQ at discharge for all groups (disengaged  $R^2=0.21$ ,  $p<0.001$ ; transfer of care  $R^2=0.18$ ,  $p<0.001$ ; treatment complete group  $R^2=0.38$ ,  $p<0.001$ ).

However this is in part an arithmetic effect, since low initial PHQ scores have less scope for absolute change than higher scores. Expressing change during treatment as the “percentage change” (i.e. change in PHQ score during treatment divided by PHQ at referral) eliminates most of this effect. However there is still a significant association between higher PHQ scores at referral and percentage reduction in PHQ score (treatment complete group  $R^2=3.2\%$ ,  $p<0.001$ ). Figure 5-20 shows mean percentage reduction in PHQ for different categories of PHQ scores at referral.

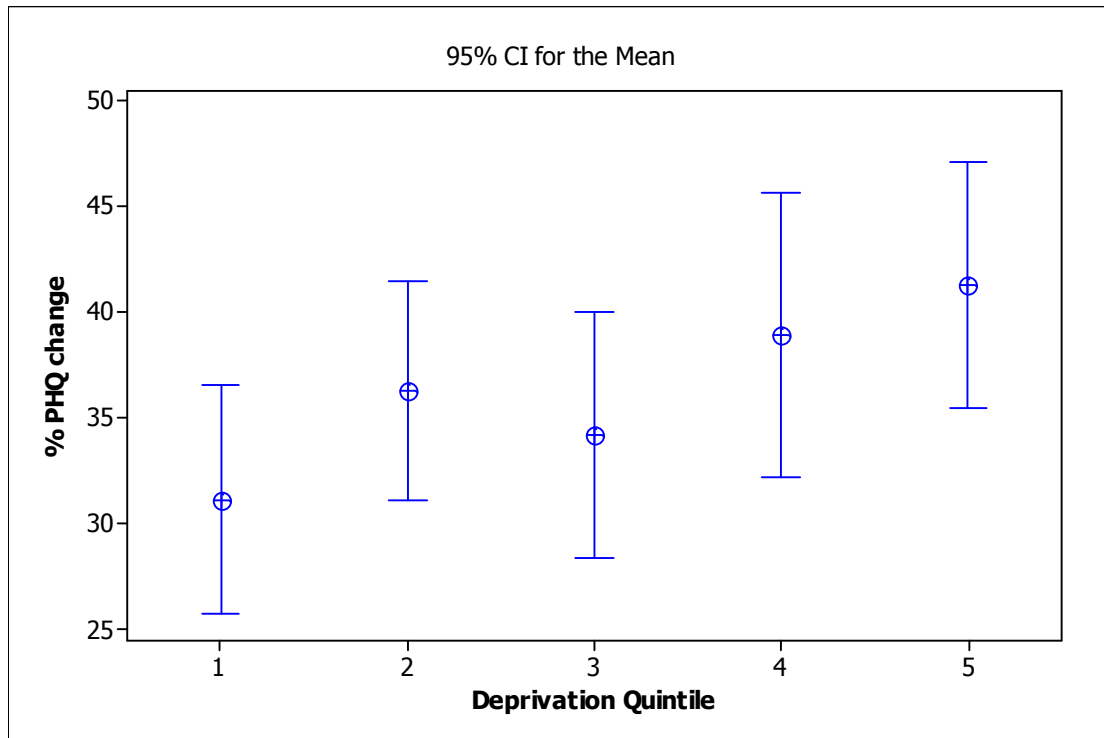


**Figure 5-20:** interval plot showing means (circles) and 95% confidence intervals (bars) for PHQ at referral against percentage change in PHQ (treatment complete group only n= 654).

#### 5.2.2.4 Deprivation

A normal linear regression model was used to examine the association between the deprivation and reduction in PHQ after treatment. The model suggested that patients living in the most deprived areas were more likely to show the least clinical improvement ( $p=0.020$ ). Although statistically significant, the effect was small (regression coefficient of 2.32,  $R^2=0.5\%$ ), and not evident when the outcome categories were examined individually (“disengaged”  $R^2=0.1\%$ ,  $p=0.52$ ; “transfer of care”  $R^2=1.0\%$ ,  $p=0.17$ ; “treatment complete”  $R^2=0.2$ ,  $p=0.22$ ). The relationship between percentage reduction in PHQ and deprivation

scores are represented in Figure 5-21 for the “disengaged”, “transfer” and “treatment complete” groups, and in Figure 5-22 for the “treatment complete” group alone .



**Figure 5-21: interval plot showing means (circles) and 95% confidence intervals (bars) for influence of deprivation on PHQ change for “disengaged”, “transfer” and “treatment complete” groups. 1 is the most and 5 the least deprived quintile.**

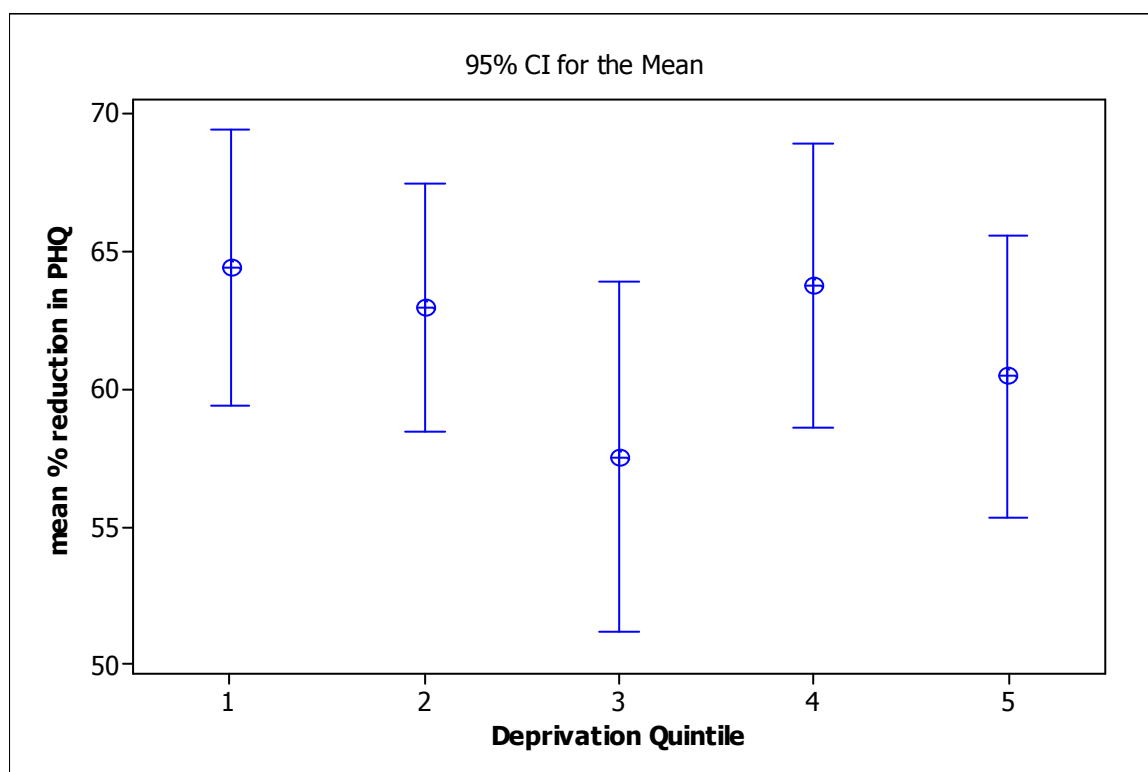
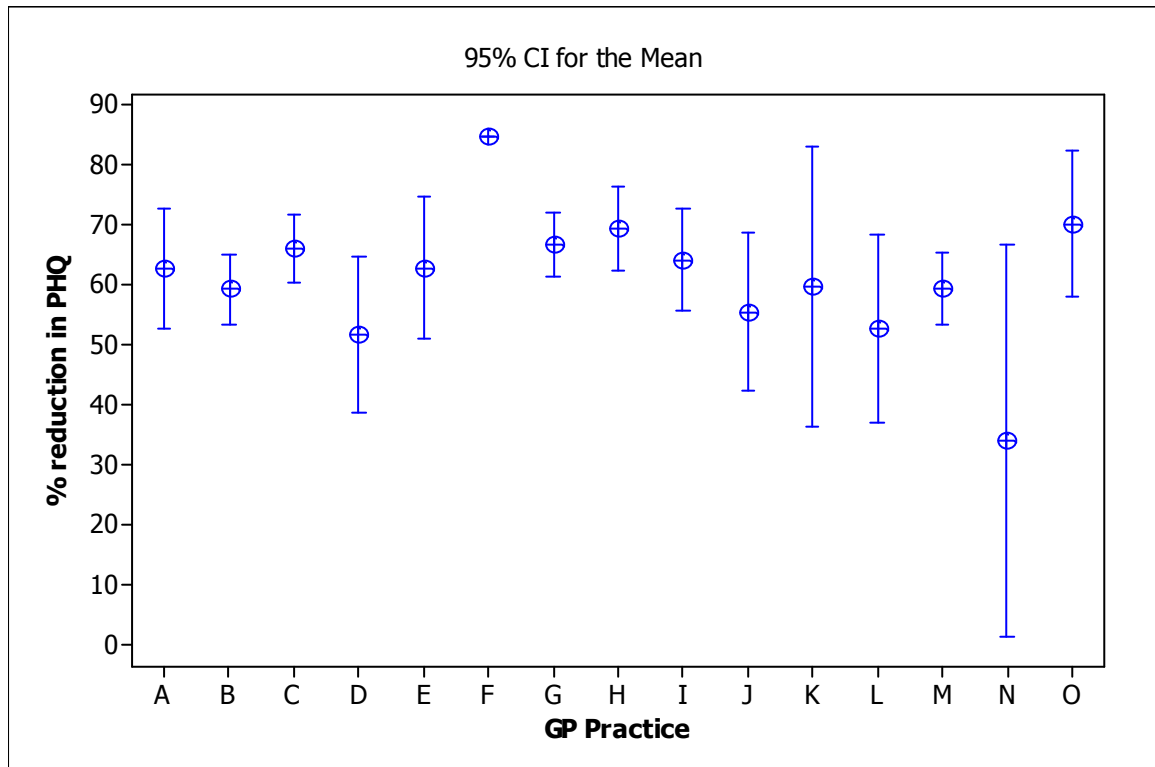


Figure 5-22: interval plot showing means (circles) and 95% confidence intervals (bars) for influence of deprivation on PHQ change in the treatment complete group only; 1 is the most and 5 the least deprived quintile.

#### 5.2.2.5 GP practice

There was no significant association between GP practice and clinical outcome as expressed by “percentage PHQ change”. Figure 5-23 shows an interval plot of PHQ change for patients in each participating GP practice.



**Figure 5-23:** interval plot showing means (circles) and 95% confidence intervals (bars) for percentage change in PHQ by GP practice for the “treatment complete” group, n=654.

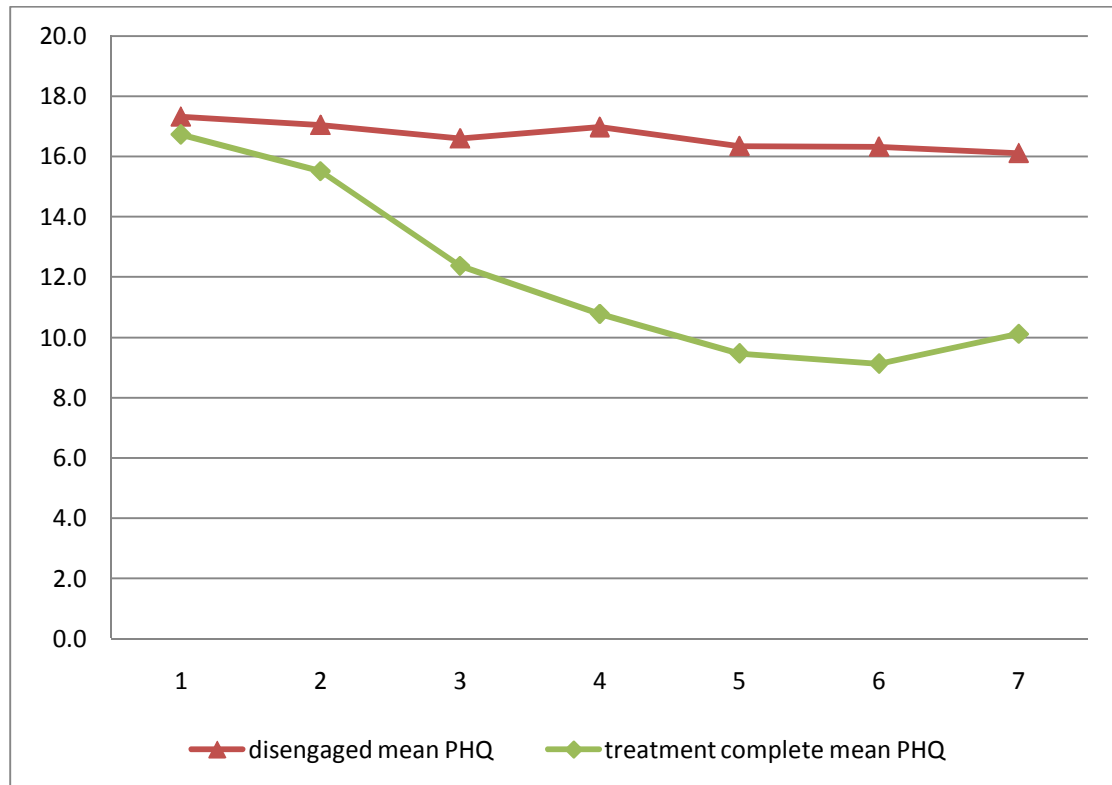
#### 5.2.2.6 Number of visits

A similar pattern is observed when the mean PHQ change is plotted for each patient contact. Subjects who subsequently disengaged from treatment showed little early change in their PHQ scores, unlike those in the treatment complete group (Figure 5-24).

By contrast, there is a clear reduction in PHQ score at each visit after the first for the treatment complete group. Most people were discharged from Doing Well with a fall in PHQ to around ten or below. Most people achieved this fall in PHQ within four or five treatment



contacts. A minority of patients required a much longer period of contact to achieve the same PHQ reduction.

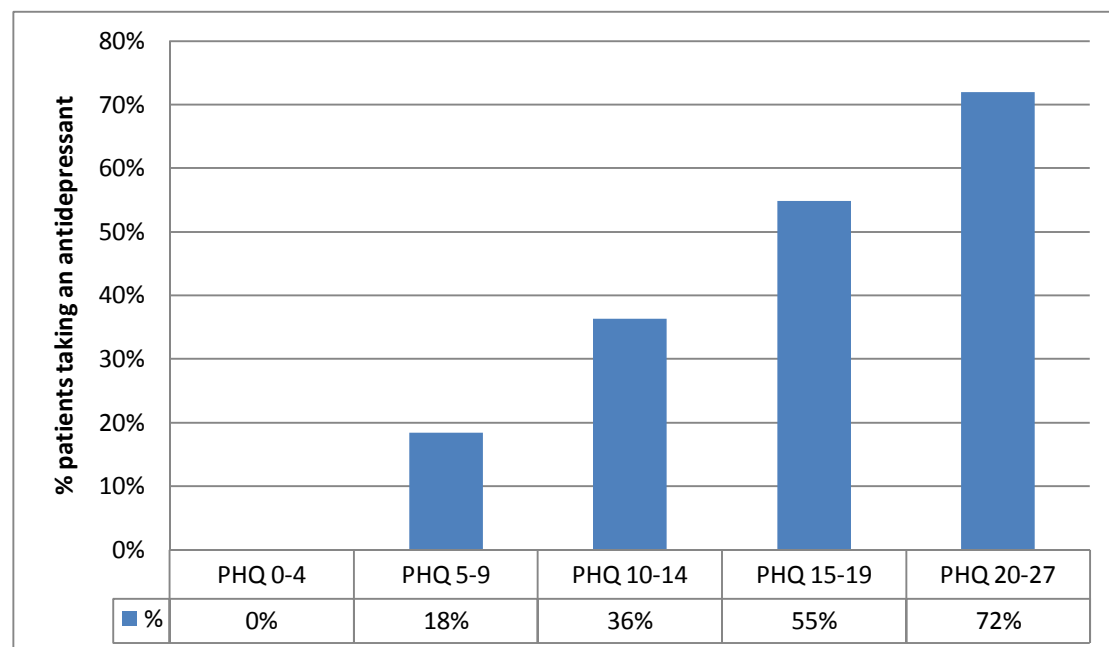


**Figure 5-24:** Graph showing mean PHQ scores and number of subjects at each contact point (1= referral PHQ) for disengaged and treatment complete groups. Data not shown for contacts beyond 7 as  $n < 20$  in disengaged group.

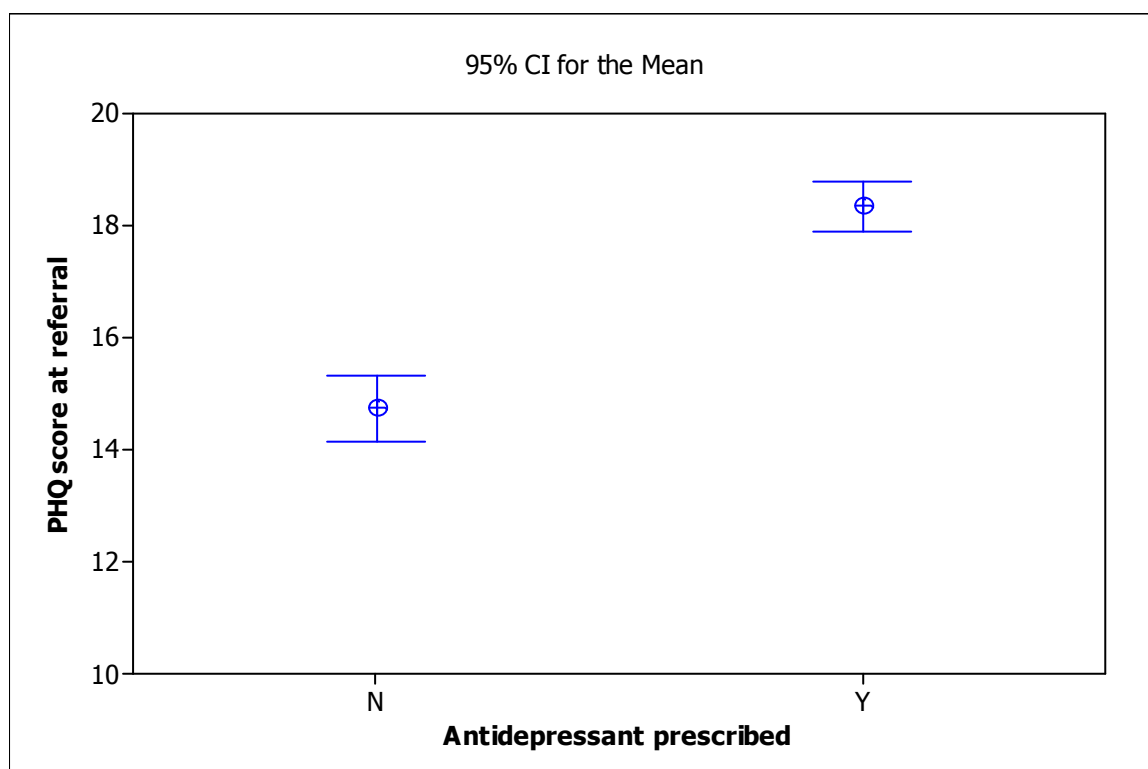
### 5.2.3 Antidepressant use

#### 5.2.3.1 Antidepressant use and PHQ score

There was a clear correlation between the severity of the PHQ score at referral and the likelihood of receiving an antidepressant prescription (Figure 5-25). PHQ scores at referral were significantly higher in patients taking antidepressants at some point during treatment ( $p<0.001$ , 95% CI for difference -4.1, -3.0; Figure 5-26).



**5-25: percentage of patients receiving an antidepressant prescription by PHQ score**  
 (total subjects 1169; PHQ 0-4 n=10; PHQ 5-9 n=76; PHQ 10-14 n= 259; PHQ 15-19  
 n=408; PHQ 20-27 n=385)



5-26: graph showing relationship between PHQ score at referral and patients taking (Y, n=358) or not taking (N, n=283) an antidepressant during treatment for treatment complete group. 13 missing data points. NB y axis does not cross at zero.

### 5.2.3.2 Antidepressant use and deprivation

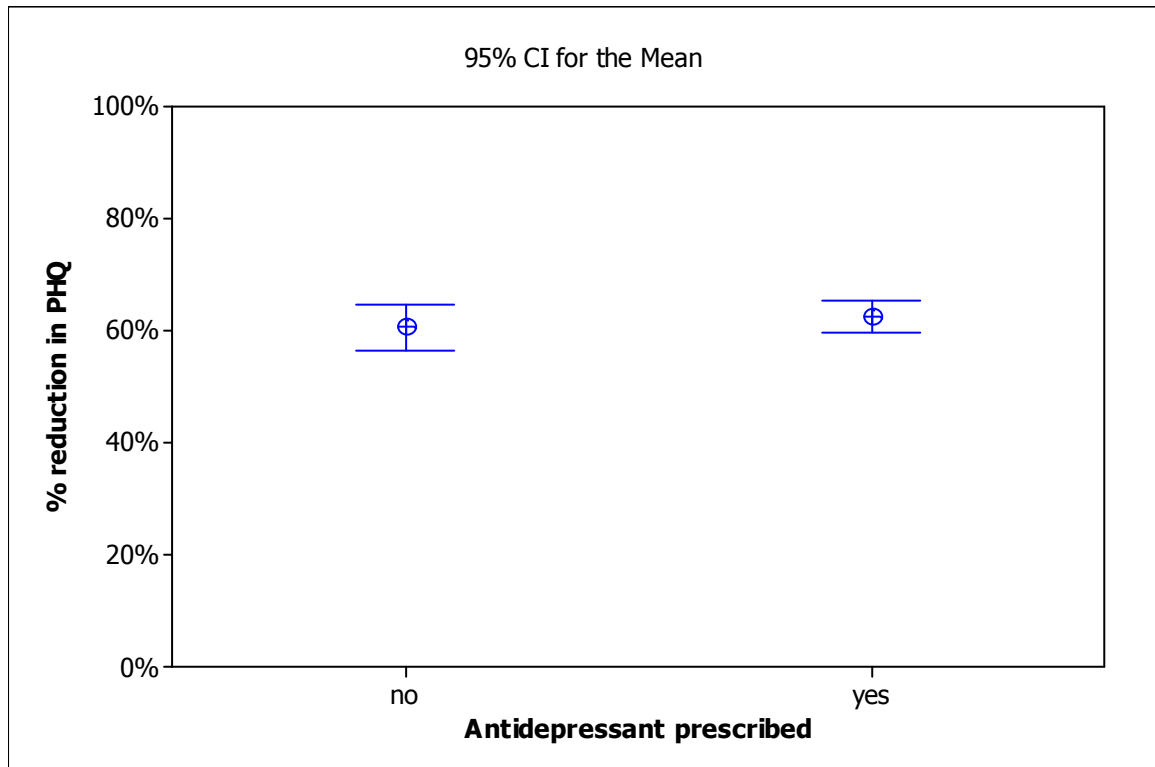
There was no significant correlation between the mean deprivation decile for patients referred in each practice and the proportion of patients from that practice who received an antidepressant (Pearson's  $r = -0.07$ ,  $R^2 = 43\%$ ,  $p = 0.82$ ).

### 5.2.3.3 Antidepressant use and clinical outcomes

641 of 654 subjects in the treatment complete group had their antidepressant use recorded at the beginning of treatment. Self-reported antidepressant initiation or concordance was recorded at each subsequent Doing Well visit.

People who took an antidepressant in the treatment complete group showed a mean fall in their PHQ score by end of treatment of 11.71 points, whereas those who did not take an antidepressant showed a fall of 9.20 points (paired t-test  $p < 0.001$ , 95% CI for difference: -3.423, -1.588).

However, once again, analysis of the mean fall in PHQ is confounded by the fact that higher PHQ scores have more scope to reduce than lower scores, and patients with higher PHQ scores were more likely to be prescribed an antidepressant. Repeating this analysis but using percentage PHQ change rather than absolute PHQ change did not show any significant difference between patients who did or did not take an antidepressant ( $p = 0.415$ , 95% CI for difference -6.91, 2.86; Figure 5-27).

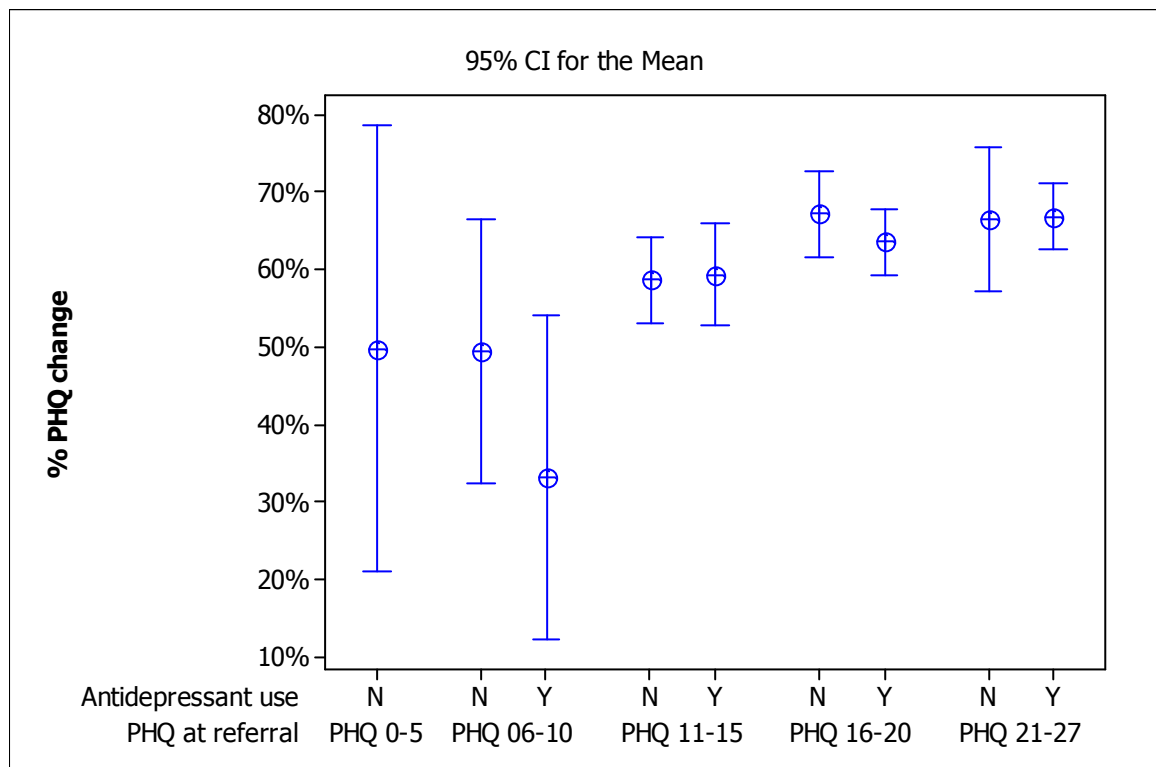


**Figure 5-27: mean and 95% confidence intervals for percentage PHQ change over baseline for treatment complete group. No= no antidepressant prescribed (n=283); Yes= antidepressant prescribed (n=358); 13 missing data points**

An analysis of antidepressant effect was not carried out for the disengaged and treatment complete groups, since they may not have taken antidepressants for a sufficient period to gauge an effect of treatment.

The mean percentage PHQ change is shown for people who did and did not take antidepressants in Figure 5-28 for different categories of PHQ score at referral. As discussed above, the severity of depression at referral (plotted on the x axis) was associated with the amount of change in PHQ over the duration of treatment. However antidepressant use was not associated with a statistically significant effect for subjects with equivalent depression

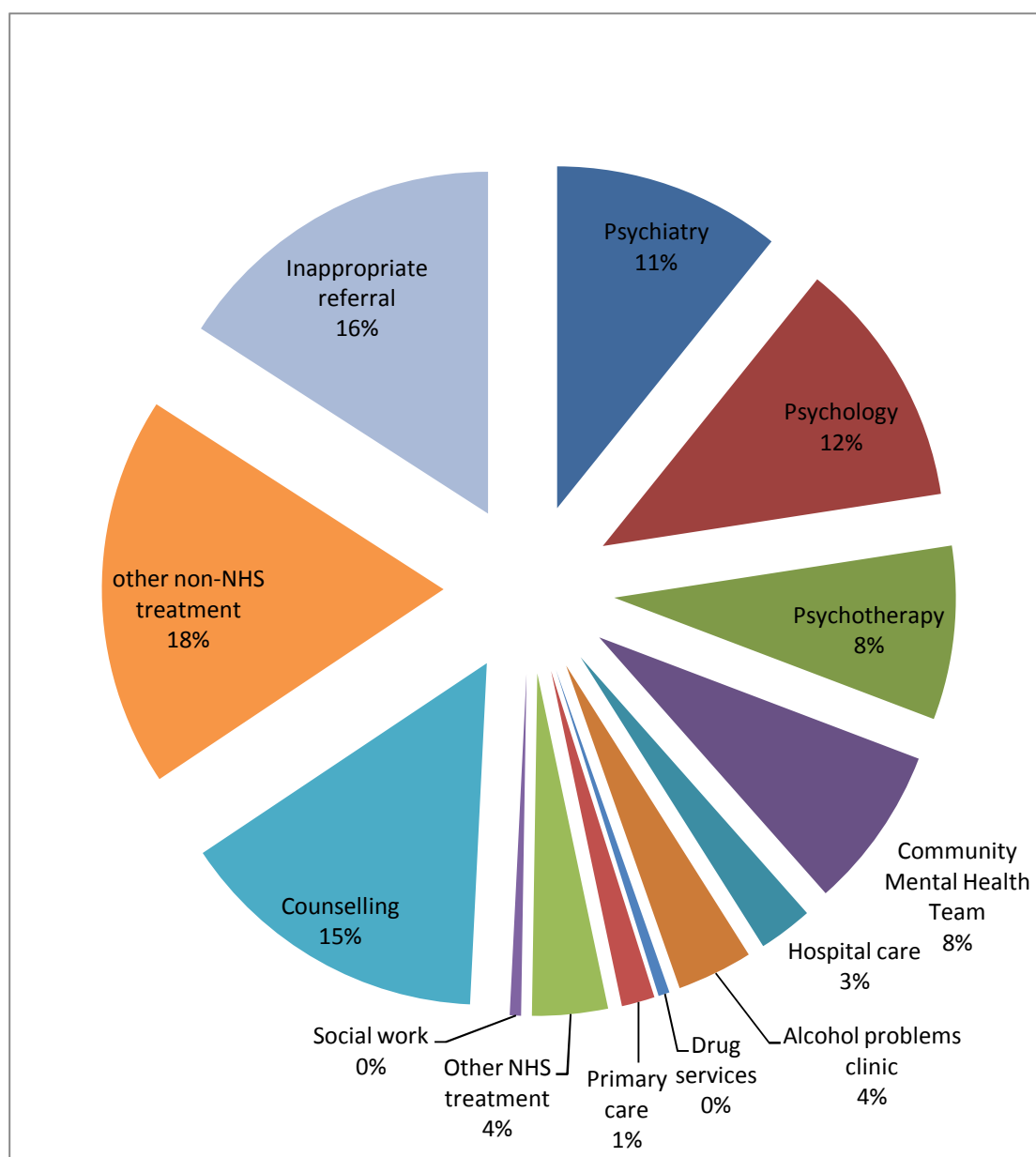
severity at referral. However data was only available to show whether the patient was taking an antidepressant at some point during contact with Doing Well, and there is no information to record dose or concordance. This data is therefore not robust enough to be analysed further.



**Figure 5-28: Percentage PHQ change from referral to discharge, shown by PHQ at referral and antidepressant use (“N”= no antidepressant prescribed, n=253; “Y”=antidepressant prescribed, n=358; 13 missing data points). Bars show 95% confidence intervals.**

### 5.2.4 Transfer of care

One hundred and ninety-five people (13%) were transferred to other services for ongoing care (represented in Figure 5-29). Of this group, 21 (11%) were referred to psychiatry, 23 (12%) were referred to psychology and 16 (8%) referred to psychotherapy. Psychiatry, psychology and psychotherapy therefore took over the care of 1.4%, 1.5% and 1.1% respectively of the 1501 eligible referrals respectively.



**Figure 5-29: services used for the 195 patients (13% of eligible subjects) transferred requiring non-""Doing Well" care**

The Community Mental Health Team received 15 transfers from Doing Well, which represents 1.0% of all eligible patients referred to Doing Well. Thirty-one patients (16% of all transfers) were referred back to their GP because they required further management for problems other than depression. Twenty-nine patients (14.9% of transfers of care) were referred on for counselling outside the NHS, and 36 patients (19% of transfers of care) were referred on for other treatment outside the NHS. A common source of referrals was to a local employment support service; other resources included a local authority funded family support centre, support groups run by the local voluntary sector and benefit and housing advice centres.



## 5.3 Prescribing change

Prescribing information in this section includes data from the study period used to describe clinical outcomes (July 04 to Oct 06) but has been extended to June 2008, so as to include more information about population prescribing available at the time of analysis. This allows for a fuller evaluation of prescribing trends than the more limited clinical dataset affords, and takes account of any latency in effect from the introduction of a new service to any possible change in prescribing.

### 5.3.1 *Defined Daily Doses*

Figure 5-30 shows the change in defined daily doses (DDDs) of antidepressants prescribed in four areas: the practices participating in this evaluation (“DW”), the practices in the rest of Renfrewshire who did not have access to the clinical service (“non-DW”), Inverclyde (which does not include Renfrewshire) and Scotland as a whole.

Note that the Scottish data includes the Doing Well practices, since it was not possible accurately to remove these practices from the national dataset. Since the Doing Well practice population (76,013) represents only 1.49% of the General Register Office mid-year 2006 estimate for the Scottish population (5,116,900), any effects will be minimal, and will tend to underestimate the effect of any change as a result of Doing Well.

It can be seen that the Doing Well practices prescribed slightly more than the Scottish average in the year prior to the Doing Well programme beginning. As the programme recruited the fourteen practices by August 2005, the defined daily doses prescribed began to fall below the Scottish average, and continue to diverge through to the end of this period in June 2008.

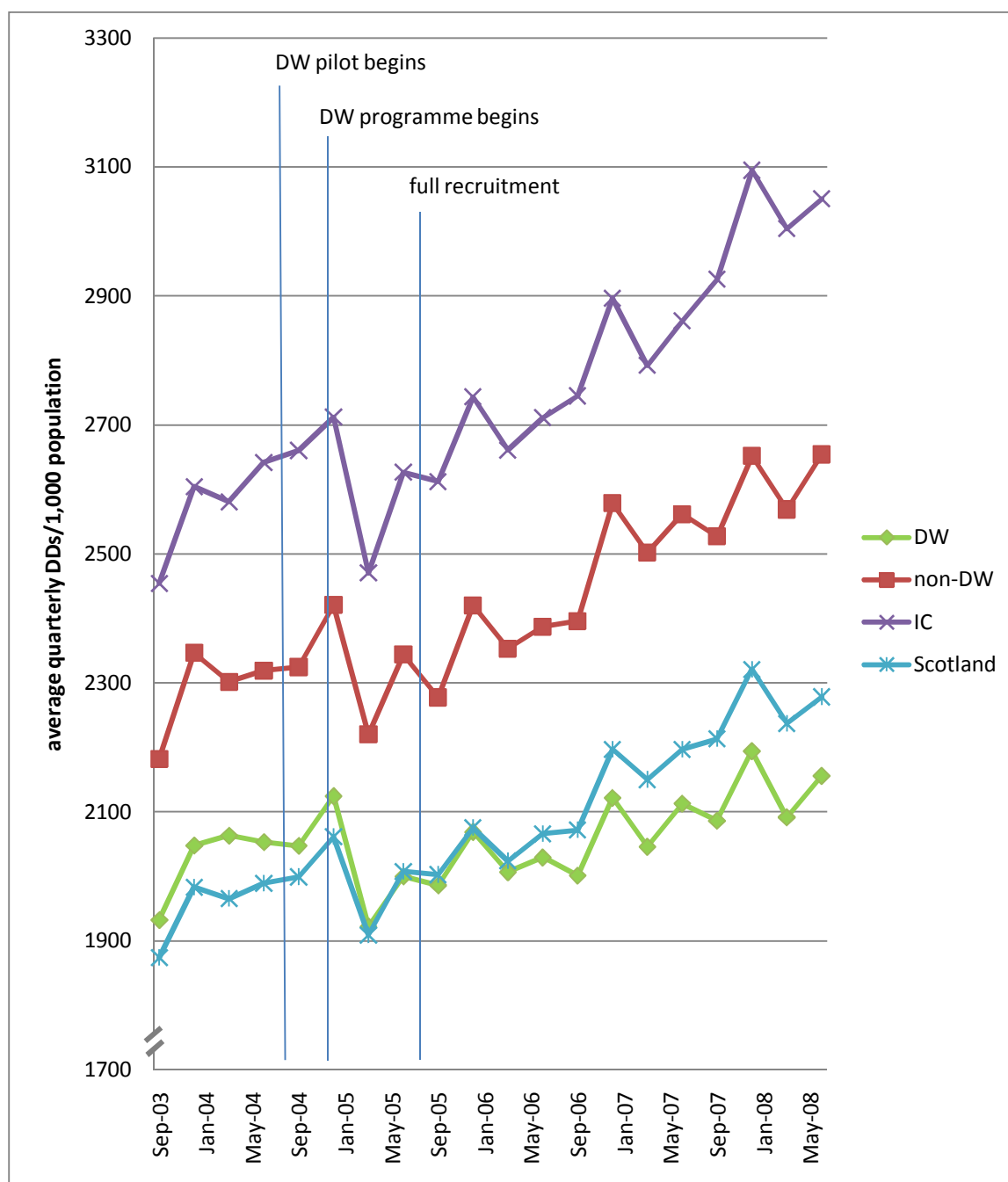


Figure 5-30: mean defined daily doses (DDD) prescribed per 1,000 population for the each quarter between July 2003 and June 2008 for Doing Well (DW) practices, neighbouring practices in Renfrewshire (non-DW), Inverclyde and Scotland. Note y axis does not cross at z

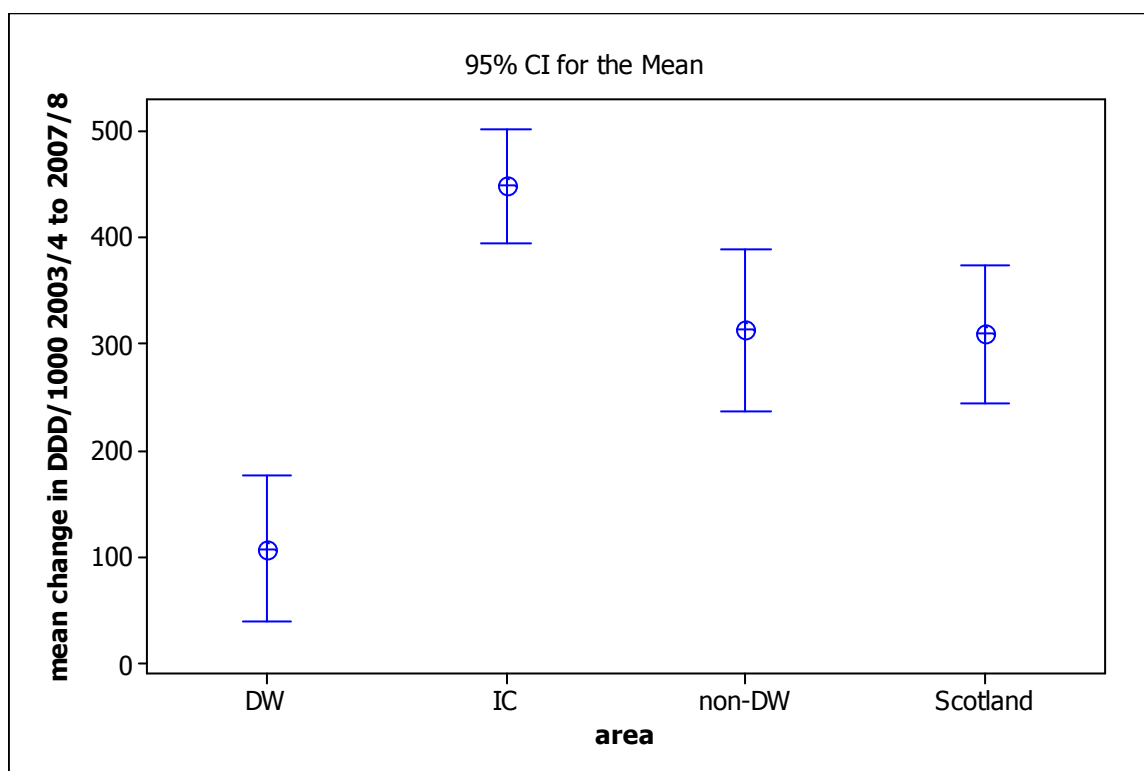
By contrast, prescribing in the non-Doing Well Renfrewshire practices and in Inverclyde continued to increase, broadly in keeping with the Scottish national average. Prescribing in both these areas was significantly higher than the national average or that in the Doing Well practices before the programme began.

The mean DDD/1000 for each of the twelve months before the Doing Well intervention (July 03 – June 04) were compared with the twelve months to June 08 using paired samples t-tests. Significant changes in Defined Daily Doses of antidepressants prescribed before and after the Doing Well intervention were observed in all the areas of interest. However, the mean change was much less in the Doing Well practices compared with “control” areas.

area	Mean change in DDD/1000	Standard Deviation	95% Confidence Intervals	t	p
Doing Well	107.8	108.1	39.1- 176.5	3.5	0.005
Non-Doing Well	313.2	119.2	237.5- 389.0	9.1	< 0.001
Inverclyde	448.6	84.1	395.2- 502.0	18.5	< 0.001
Scotland	309.4	101.8	244.7- 374.2	10.5	< 0.001

**Table 5-5: mean change in monthly DDDs/1000 population before (July 2003 to June 2004) and after (July 2007 to June 2008) the Doing Well Intervention.**

The same information is also presented graphically in Figure 5-31.



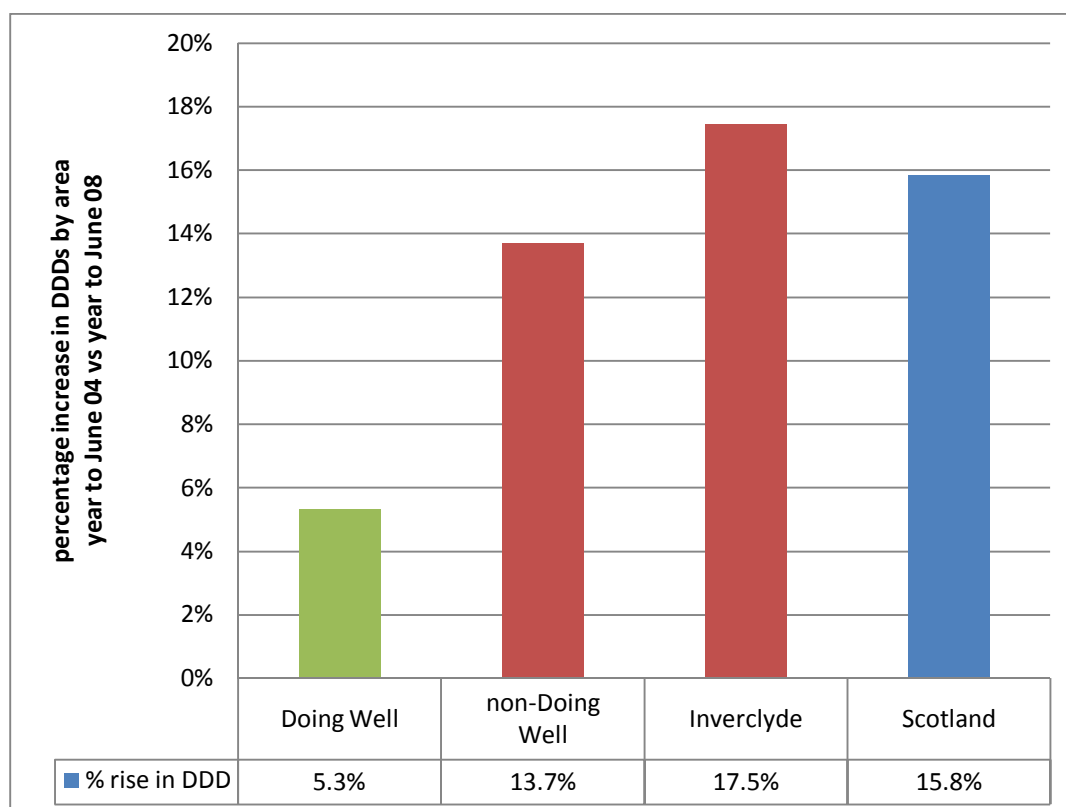
**Figure 5-31: increase in DDD/1000 population between 2003/4 and 2007/8 for four areas of interest. DW= “Doing Well”, IC= Inverclyde, non-DW= “non-Doing Well”**

Comparison of between-group increases in prescribing over the same period using one-way ANOVA showed significant differences ( $F=13.71$ ,  $p<0.001$ ). The increase observed in Doing Well practices was significantly less than that seen in non-Doing Well, Inverclyde and Scotland-wide areas ( $p<0.001$  for all; 95% confidence intervals shown in Figure 5-32). There were no significant difference in change in prescribing over this period between the non-Doing Well and Scottish practices ( $p=0.996$ ). However, Inverclyde showed a significantly higher increase in prescribing than any other control area ( $p<0.02$  for all).

		Differences in mean DDD/1000	p	95% Confidence Intervals
DW compared to	Non-DW	-205.4	< 0.001	-322.8- -88.0
	Inverclyde	-340.8	< 0.001	-458.2- -223.4
	Scotland	-201.6	< 0.001	-319.0- -84.2
Non-DW compared to	DW	205.4	< 0.001	88.0 - 322.8
	Inverclyde	-135.3	0.016	-252.8- -17.9
	Scotland	3.8	1.000	-113.6- 121.2
Inverclyde compared to	DW	340.8	< 0.001	223.4- 458.2
	Non-DW	135.3	0.016	17.9- 252.8
	Scotland	139.1	0.012	21.7- 256.5
Scotland compared to	DW	201.6	< 0.001	84.2- 319.0
	Non-DW	-3.8	1.000	-121.2- 113.6
	Inverclyde	-139.1	0.012	-256.5- -21.7

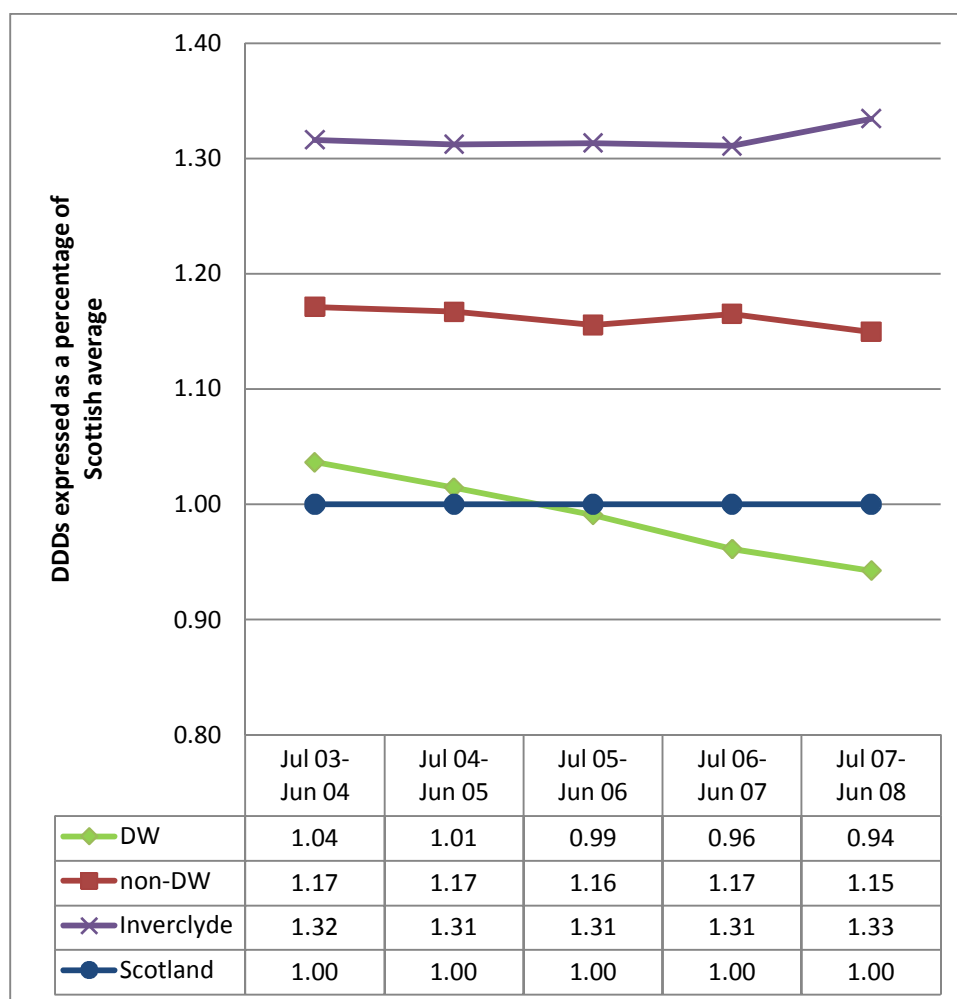
**Figure 5-32: Between-group comparison for change in Defined Daily Doses in Doing Well and control areas 2003-4 to 2007-8**

Figure 5-33 shows the increase in average DDDs for practices in the Doing Well programme and neighbouring geographical areas between the 12-month period before Doing Well started to recruit practices (July 2003- June 2004) and the 12 months to June 2008. There was a 5.3% rise in antidepressant use in the Doing Well area, compared with a 15.8% increase in Scotland, and significant rises in neighbouring areas.



**Figure 5-33: percentage change in Defined Daily Doses (DDDs) from July 03-Jun 04 to July 06-Jun 08 by area**

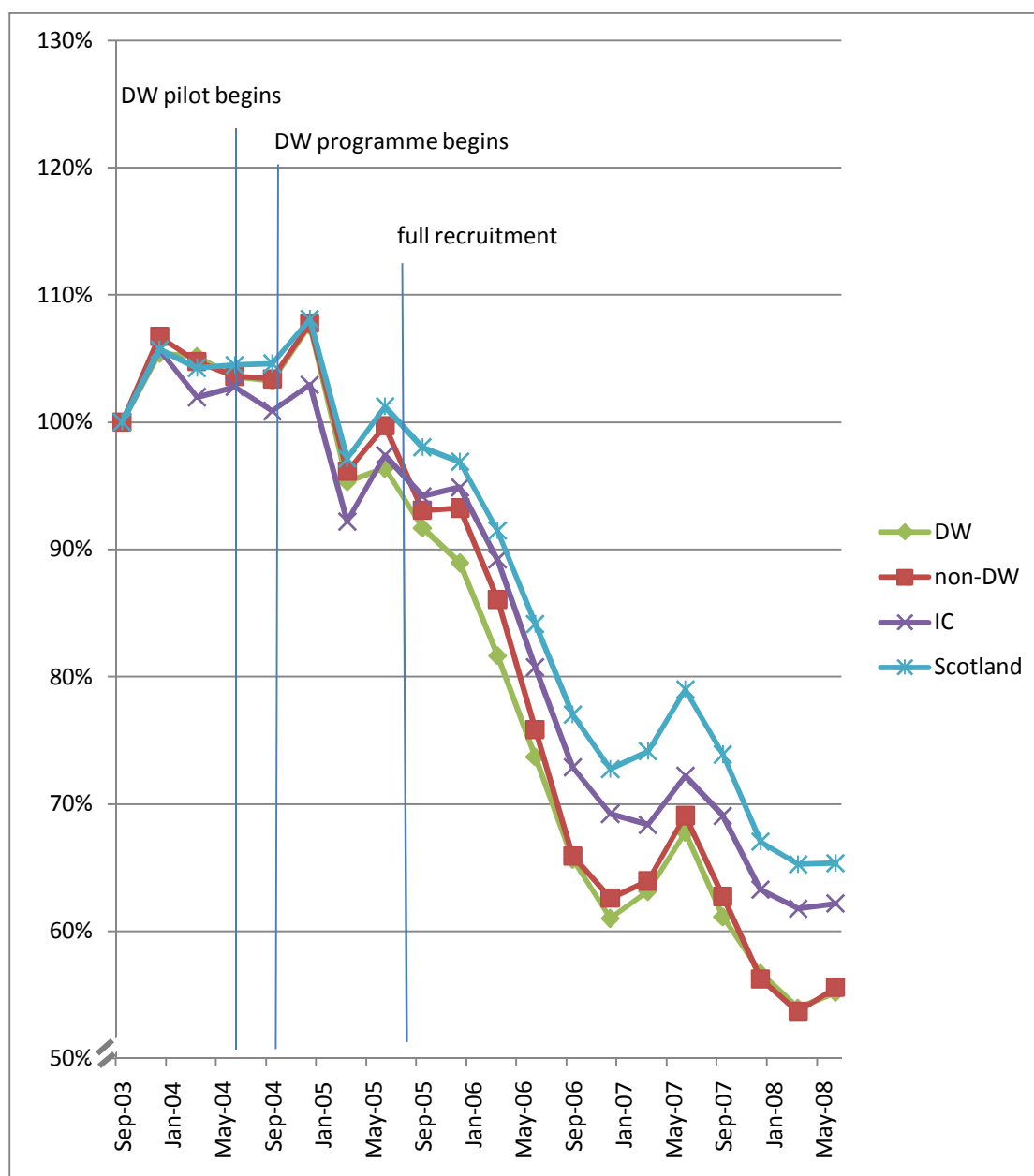
Figure 5-34 represents the prescribing rate of DDDs per capita relative to the Scottish national average for each of the five years from July 2003 to June 2008. Prior to the advent of Doing Well, those practices prescribed above the Scottish average, although markedly below other practices in neighbouring areas. However while those other practices maintained their relative position, prescribing in Doing Well practices fell below the national average from the year 2005-6 onwards.



**Figure 5-34: Defined Daily Doses per capita relative to Scottish average, July 2003-June 2008**

### 5.3.2 Gross Ingredient Cost

Figure 5-35 shows the fall in Gross Ingredient Cost (GIC) by quarter, standardised to costs in the quarter July-September 2003. The fall in costs was very similar for both Doing Well (to 55% of baseline) and non-Doing Well practices (to 56% of baseline). These reductions were significantly more than the reductions in cost seen in Inverclyde (62% of baseline) or in Scotland as a whole (65% of baseline).

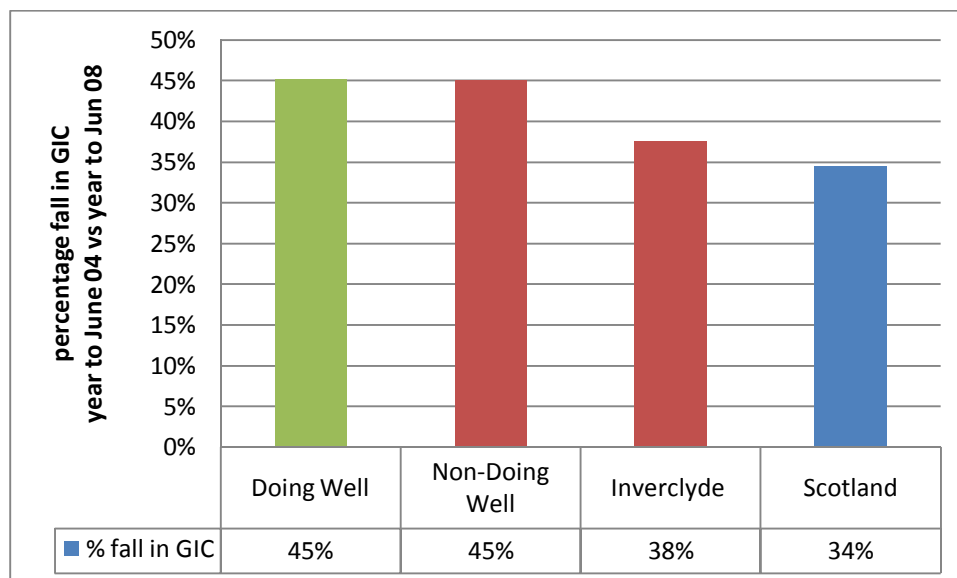


**5-35: relative fall in Gross Ingredient Cost, standardised to costs in the quarter July-Sept 03 by area. Note y axis does not start at zero.**

Figure 5-36 summarises this reduction in the average Gross Ingredient Cost (GIC) of antidepressants prescribed between the twelve months to June 2004 and the twelve months to June 2007. The fall in GIC was significantly greater for the Renfrewshire practices (both



Doing Well and non-Doing Well), compared with the falls seen in Inverclyde and Scotland as a whole.



**Figure 5-36: Percentage reduction in total Gross Ingredient Cost (GIC) from July 03-June 04 to July 07-June 08 by area**

Table 5-6 shows the within-group reductions in mean gross ingredient cost (GIC) over this period, with paired samples t-tests used to examine differences between mean gross ingredient cost during the 12 months to July 2004 and the 12 months to July 2008. The within-group differences are all highly significant ( $p < 0.001$  for each).

area	Mean reduction in GIC dispensed	Standard Deviation	95% Confidence Intervals	t	p
Doing Well	-34593.9	4801.5	-31543- -37644	25.0	< 0.001
Non-Doing Well	-54042.9	8322.0	-48755- -59330	22.5	< 0.001
Inverclyde	-40742.9	5984.9	-36940- -44545	23.6	< 0.001
Scotland	-1690128.2	345054.1	-1470891- -1909365	17.0	< 0.001

**Table 5-6: Within-group comparison for change in total Gross Ingredient Cost (GIC) in Doing Well and control areas between July 2003-June 2004 to July 2007-June 2008**

Table 5-7 shows a between-group comparison for the four geographical areas. There is no statistically significant difference between the fall in Gross Ingredient Cost observed in both the Doing Well and non-Doing Well areas ( $p=1.000$ ), but this was significantly greater than the fall seen in Inverclyde ( $p=0.004$ ) and Scotland as a whole ( $p<0.001$ ). Inverclyde and Scotland showed statistically similar reductions in Gross Ingredient Cost ( $p=0.446$ ).

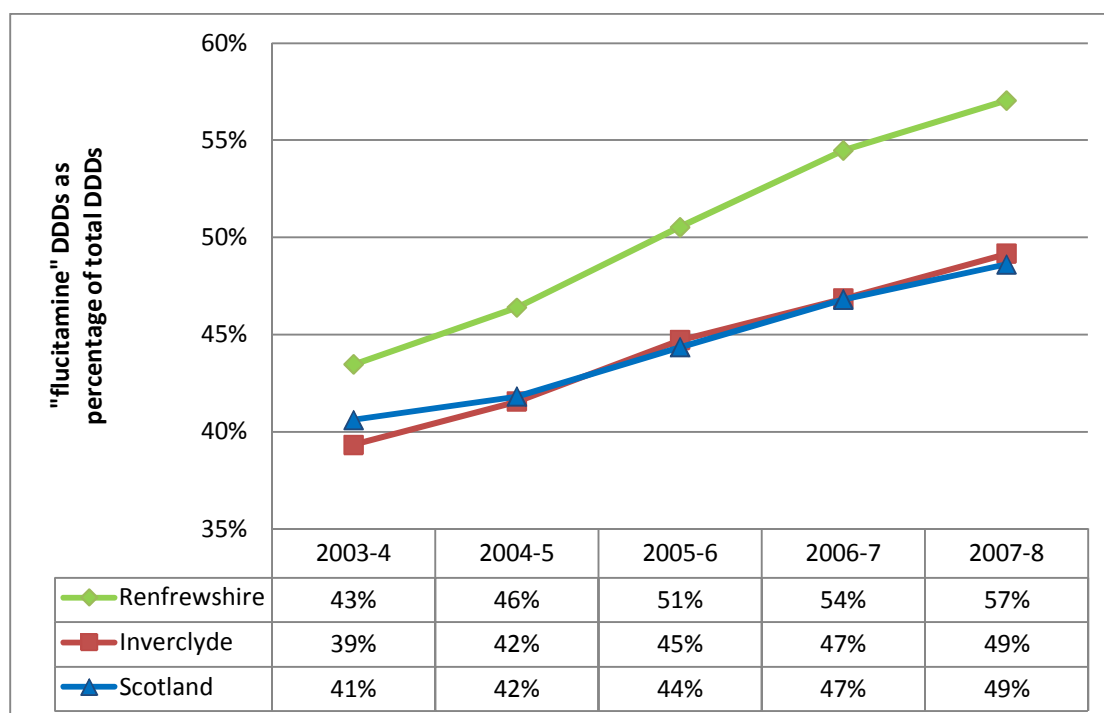
		Mean % change in GIC	p	95% Confidence Intervals
DW compared to	Non-DW	0.18%	1.000	-5.39- 5.76
	Inverclyde	7.59%	0.004	2.01- 13.17
	Scotland	10.73%	< 0.001	5.15- 16.30
Non-DW compared to	DW	-0.18%	1.000	-5.76- 5.39
	Inverclyde	7.41%	.005	1.83- 12.99
	Scotland	10.54%	< 0.001	4.96- 16.12
Inverclyde compared to	DW	-7.59%	0.004	-13.17- -2.01
	Non-DW	-7.41%	0.005	-12.99- -1.83
	Scotland	3.13%	0.446	-2.44- 8.71
Scotland compared to	DW	-10.73%	< 0.001	-16.30- -5.15
	Non-DW	-10.54%	< 0.001	-16.12- -4.96
	Inverclyde	-3.13%	0.446	-8.71- 2.44

**Table 5-7: Between-group comparison for change in Gross Ingredient Cost (GIC) in Doing Well and control areas 2003-4 to 2007-8**

### 5.3.3 *Formulary compliance*

Antidepressants approved in the formulary (fluoxetine, citalopram and lofepramine) were amongst the cheapest available at that time. Since there was not a significant difference between Doing Well and neighbouring Renfrewshire practices in terms of formulary prescribing, data for these practices is shown together in the following graphs. Data for Scotland is shown for comparison purposes, but it should be noted that antidepressant formularies vary between Health Boards. All Scottish Health Boards recommend fluoxetine as a first line drug; citalopram is frequently also a first-line option, and is always included as a second-line choice. Lofepramine is mentioned specifically in a minority of Board formularies.

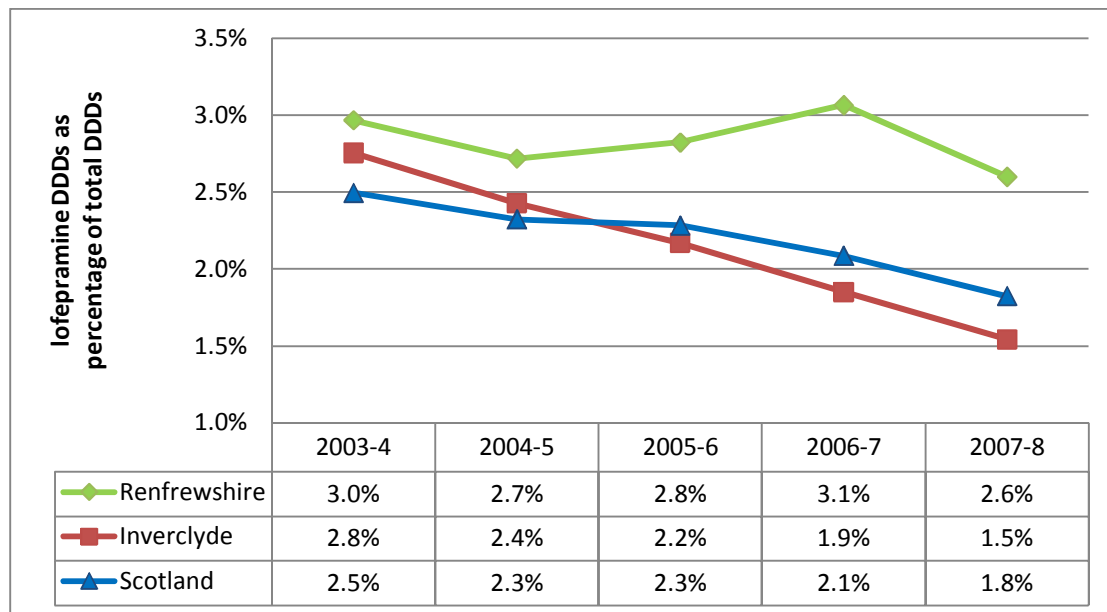
Figure 5-37 shows that the proportion of formulary drugs prescribed as a percentage of all prescribed antidepressants increased more rapidly in Renfrewshire (from 43% to 57%) than in Inverclyde (39% to 49%) or in Scotland as a whole (41% to 49%). The change in prescribing within each area between the 12 months to June 2004 and the 12 months to June 2008 was statistically significant (paired t-tests,  $p < 0.001$ ). This will account for some of the reduction in costs noted above. Between-group comparisons using one-way ANOVA showed that the differences between Renfrewshire, Inverclyde and Scotland were all highly significant ( $p < 0.001$ ).



**Figure 5-37: fluoxetine, citalopram and lofepramine prescribed as a percentage of total antidepressant prescriptions per 12 month period, July 04 to July 08**

Figure 5-38 shows that the use of lofepramine been declining in Scotland and Inverclyde. However this drug showed relatively modest decreases in Renfrewshire. Paired t-testing of within-area change between the year to July 2004 and the year to July 2008 showed a statistically significant reduction in lofepramine use in all areas ( $p < 0.001$ ). Differences between Renfrewshire and Inverclyde (which share the same formulary) were highly significant ( $p < 0.001$ ).

This suggests that prescribing practice in Renfrewshire did diverge from that in Inverclyde and Scotland over this period. Since Inverclyde and Renfrewshire shared the same formulary, the difference observed may have been related to the work done by Doing Well in Renfrewshire to promote the use of these drugs.



**Figure 5-38: lofepramine prescribed as a percentage of total antidepressant prescriptions per 12 month period, July 04 to July 08**

## 6. Discussion

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### 6.1 Chapter outline

This thesis describes the implementation of “Doing Well”, a programme designed to deliver depression care for a population of 76,000 people in 14 general practices in Renfrewshire, Scotland. This was an area that had previously had little input from community mental health services, so the relative lack of provision provided an opportunity to design, implement and evaluate an entirely new service.

Three main steps were required to implement the Doing Well programme as part of the Centre for Change and Innovation’s drive for quality improvement:

1. To understand what best practice in depression care might be, and to resolve gaps or uncertainties in clinical evidence
2. To design and then implement a system of care that could reliably deliver effective treatment in a safe way
3. To design a system that was able to find a sustainable niche within the network of existing service provision, and was suitable for generalisation to other areas and different settings

Each of these steps presented their own challenges, and each was resolved in different ways; sections 6.2 and 6.3 discuss the limitations and strengths of the study respectively.

A large research literature has established the effectiveness of pharmacological and psychological treatments for some people with depression in some settings, and this is

reflected in NICE guidance about appropriate interventions. But there are still substantial gaps in our knowledge. How, for example, should we seek to predict whether psychological or pharmacological treatment would be most appropriate for a patient presenting with a new case of low mood? What are the optimal frequency, intensity and duration of psychological treatments? Which of the 25 NICE treatment recommendations are indispensable, and which “packages” of different interventions would represent optimal care?

This study was a limited evaluation of a complex intervention. The research challenges presented by this type of intervention are discussed in section 6.4. The clinical outcomes and prescribing change associated with the implementation of the Doing Well programme are then discussed in sections 6.6 and 6.7 respectively.

There is an acknowledged gap between our knowledge of the best available treatments, and the care that is actually delivered in practice. This gap can only be bridged by careful attention to healthcare systems design.<sup>113</sup> Section 6.8 reflects on the difficulties of managing uncertainty in practice, and section 6.9 examines how health services can design and implement systems to support effective decision-making and quality care.

## 6.2 Limitations of this study

### 6.2.1 Study design

The national Doing Well by People with Depression programme was intended to be a complex health and social care intervention that required local systems to change the way they delivered care. The national evaluation was designed as a “formative comparative case study” using a range of methods, including “workshops, significant event analysis and the use of routine audit and outcome data to review and improve practice”.<sup>333</sup> The programme did not ask participating areas to formulate or answer research questions, and there was no government support or funding for randomised controlled trials.

This study was therefore developed with an observational design, without a control group for the clinical intervention. As will be discussed in section 6.4, this approach may have some advantages over randomised controlled trials for the investigation of “complex interventions”, at least in the initial phases. Nonetheless, it was not possible to compare directly the outcomes for patients receiving care from Doing Well with those receiving “treatment as usual”.

Lack of a control group may be especially problematic in studies of depression, since mild to moderate episodes tend to remit spontaneously, with a median time to recovery of 12 weeks or less.<sup>334</sup> Whether psychological or pharmacological interventions are being evaluated, it is likely that 50% of subjects will recover within 8 weeks.<sup>335</sup> Furthermore, the placebo effect in antidepressant trials is unusually large- accounting for about 60% of the improvement shown by active drug groups in clinical trials.<sup>125</sup> This study has shown substantial improvement in the 654 patients out of 1,501 referred who met the eligibility



criteria. It is possible that similar improvement would have been found with treatment as usual.

Operational policies supported by clinical governance procedures in Doing Well acted to monitor and maintain appropriate standards in relation to waiting times, consultation length, number of contacts and the service response to patients who did not improve during the course of treatment. Weekly clinical meetings provided an opportunity for multidisciplinary review of complex or problematic cases, and each clinician had weekly individual supervision of their caseload. As described in the Methods section, each clinical encounter began with an introduction to the “Overcoming Depression” self-help workbook, and a standard template for the clinical history was completed. However the use of subsequent self-help modules (for the Self Help Support Workers) or psychological therapy approaches (for the Primary Care Liaison Workers) was not specified. Although clinicians were expected to work within an approved framework (of guided self-help, cognitive behavioural therapy or interpersonal therapy), the “fidelity” of adherence to these approaches was not monitored.

This lack of information about “fidelity” makes it harder to identify the “active ingredient” associated with the intervention, and limits the generalisability of this study. These are significant limitations. They reflect not only the pragmatic exigencies of an observational study carried out in routine care, but also genuine uncertainty about what type of intervention is most appropriate in this setting. As described in section 3.4.1 (*What types of therapy are effective for depression?*), there are no “specific” treatments for depression, and most clinical effectiveness relates to a limited number of “common factors”.

Section 6.4 (*The evaluation of complex interventions*) discusses how this study might be considered part of the “modelling” or “exploratory” phases of the evaluation of a complex

intervention that precede a randomised, controlled study, and reviews the issue of how “out of control” a randomised controlled trial can be.<sup>336</sup>

The changes made by Doing Well influenced not only the content and context of individual patient consultations, but also to changes in the wider system of care. These changes will have evoked a response from the catchment population and health system, which in turn influence the nature of the original intervention. It was not possible to evaluate all the factors that may have influenced the effectiveness of the programme.

For example, one consequence of Doing Well was that the waiting time for brief psychological therapy for people with depression reduced from six to twelve months to about two weeks. Referrals were also accepted for patients with any level of depression severity. These changes represent a marked increase in the accessibility of psychological therapies, and could be anticipated to make GPs more likely to make a referral. Unless this “increased demand” for a service was matched by appropriate capacity, waiting times for the Doing Well service would be expected to increase again. At some point a dynamic equilibrium will be reached between demand and supply for a service (meaning the accessibility and capacity it can provide). This study did not examine possible changes in service use or service adaptation elsewhere in the health system.

Population and prescriber behaviour in relation to depression will respond to social, political and economic factors as well as more direct health service issues. It is possible to identify a number of factors that were beyond the control of the Doing Well programme. For example, significant investment was made in local community mental health services during the period of this evaluation (which continue at the time of writing in 2010). Most of the new investment was made in West Renfrewshire, where Doing Well happened to be located. In keeping with UK policy, the NHS in Scotland also received significant additional investment

during the study period, and clinical services in NHS Argyll and Clyde were subjected to a series of high-level managerial interventions that ultimately led to the merging of South Clyde mental health services with those in NHS Greater Glasgow from April 2006. Scottish Government initiatives like the “see me” campaign against the stigma of mental illness (launched in 2003), and the national “Breathing Space” phone helpline for people with low mood (launched in 2004) may have raised the profile of depression and encouraged people to seek help.

Although none of these changes had a direct effect on the provision of primary care mental health services or psychological therapies, it is likely that general improvements in secondary care mental health services would have had some influence on the outcome for patients with depression. This study was not designed to examine ways in which such nationally-led initiatives might have influenced care for people with depression at a local level.

An expert panel of opinion has proposed that response should only be taken to have occurred when symptom reduction has persisted for three weeks or more.<sup>264</sup> Clinical protocols used in this study did not specify that outcomes should have stabilised in this way. However clinical staff did use their judgement to assess whether the “trajectory” of PHQ scores was likely to indicate a stable improvement after patient contact had ceased.

Concordance with antidepressant medicines has been noted to improve outcomes in a number of studies,<sup>337</sup> but this study was not designed to assess concordance. It is therefore not known to what extent elements of the Doing Well treatment approach which were intended to provide “compliance support” could have influenced clinical outcomes.

Data was not collected on ethnicity, disability or sexual orientation. There was no health economic evaluation. The views of patients and GPs about the service were not assessed directly.

### *6.2.2 Limitations of the prescribing measures*

High-quality data was obtained from national sources about practice-level prescribing. This allowed for analysis of the type of antidepressant, the defined daily doses and the gross ingredient cost of medicines prescribed. But since data could not be linked to individual patients at the time of this study, it was not possible to distinguish between antidepressants used to treat depression from the use of these drugs for other indications. There was significant variation in defined daily doses from month to month through the calendar year. Some of this variation is accounted for by non-random factors (like the dates of public holidays), but there is also significant “noise” in the system caused by random or unknown factors. This means that change in prescribing practice can only be assessed reliably over periods longer than one month.

### *6.2.3 Limitations of the clinical outcome measures*

The use of the PHQ to track patient response to treatment was a critical component in the Doing Well model of care evaluated here. But the use of the PHQ to guide care in this way has four potential limitations. Firstly, the PHQ score itself may be too simplistic a measure for a condition as complex and varied as depression. Secondly, technical issues relating to the sensitivity, specificity, reliability and validity of the measure may limit its clinical utility.

Thirdly, investigators need to consider whether definitions of response and remission which are based on the PHQ are appropriate or meaningful when evaluating clinical practice.

Finally, the use of the PHQ both as a “process” measure (to guide the delivery of appropriate care) and an “outcome” measure (to assess the effectiveness of treatment overall) is a potential source of bias. The PHQ was usually completed by the patient, often away from their Doing Well consultation. However at other times they would complete the PHQ during an appointment, with or without the support of their Doing Well worker. Although the PHQ was intended to assess symptom frequency in the preceding two weeks, recall bias may limit the accuracy of the scores recorded. The PHQ score might be influenced by a patient’s wish to convey difficult sentiments to the clinician (eg “I might look better, but I don’t feel ready to be discharged yet”), or be subject to (intentional or subconscious) transference reactions emerging from the patient-clinician relationship. To some extent these forms of bias and communication will be interpreted and responded to as part of the normal therapeutic process. However the PHQ as a final “outcome” measure may not be free of such influences, and yet will come to stand for the efficacy of treatment overall.

Two approaches might have minimised the influence of this potential bias. Firstly, the final “outcome” score for each patient could have been completed and recorded “anonymously” (ie away from the clinician and not communicated to them). Secondly, the use of other measures to complement the PHQ would have presented a fuller picture of “outcomes” as distinct from the process variables. Low response rates prevented their use in this study, but systematic reviews have established that a number of factors (e.g. shorter questionnaires, telephone follow-up, use of stamped addressed envelopes and first class and registered mail, University rather than health service letterheads) can improve low

response rates to questionnaires.<sup>338,339</sup> Future studies would need to take account of these findings when seeking to improve response rates.

The use of scoring systems as clinical indicators is well established within chronic disease management protocols: for example, the use of peak flow measurements in asthma care, or blood sugar levels in the management of diabetes. Part of the rationale for developing and using equivalent tools in depression is that such a chronic disease management approach is presumed to be of potential benefit in depression care.

But the scores generated by the use of depression assessment tools differ significantly from the measures used in physical health conditions. The pathophysiology of diabetes or hypertension is causally and directly linked to blood sugar and blood pressure, but there are no such biomarkers currently available for depression. The PHQ therefore measures a constellation of subjective experiences that are associated with a condition that we have called “depression”- but which has no identifiable “endophenotype”,<sup>340</sup> and for which there are very limited objective measures of severity.

Depression scoring tools like the PHQ are therefore necessarily based on clinician assessment or user self-report about a limited, pre-selected range of possible symptoms. Even though scales may have good inter-rater and test-retest reliability, sensitivity and specificity, they are based on human qualitative assessment, which is inherently variable. Evidence published since the advent of the Doing Well programme suggests that the PHQ may overestimate the severity of depression compared with other measures; this issue is discussed in more detail in section 6.8.1.3.

Depression assessment tools are inherently limited, since symptom counts of the kind recorded by the PHQ make no reference to the previous personal experience or current

living situation of the patient, even though both are highly relevant to an understanding of their current depressive symptoms. While a symptom count may be useful in determining the likelihood of response to antidepressant medicines, it has limited utility in assessing the likely response to psychological treatments. For this reason, all Doing Well assessments were based on a 40-60 minute initial assessment.

As described in section 4.4.4, these interviews enquired about a range of areas not covered by the PHQ, such as previous personal, family and medical history, medicines taken, anxiety symptoms, subjective well-being, satisfaction with treatment, understanding of treatment, and social and work functioning. An important rationale for the Doing Well clinical intervention was that patients would be offered enough time to discuss these issues with an appropriately skilled clinician. However, there was no measure of the extent to which these topics were covered during assessment and follow-up visits. Nor was there any assessment of the appropriateness of therapeutic interventions made during appointments.

This study sought to assess outcomes using measures other than the PHQ (The Work and Social Adjustment Scale (WSAS), EQ-5D and Client Satisfaction Questionnaire). But poor completion rates prevented their use in further analysis. This limited the study's ability to assess more holistic aspects of care, including functional ability, quality of life and satisfaction with treatment. The main reason for the low rates of return was that it proved difficult to acquire rating scale scores for measures not completed during the consultation. This was especially true of the Client Satisfaction Questionnaire (which was completed away from the clinician to minimise bias) and the four-month follow-up evaluation, simply because the passage of time meant that participants had other priorities. Other influences on score use and return rates are discussed in section 6.3.

#### *6.2.4 People not referred for care*

This study did not provide any information about the outcomes for those who did not attend appointments, or who dropped out of treatment. This aspect of care was not the principal focus of this evaluation. Information about subsequent progress for this group of patients will be recorded in general practice notes, but this study was not resourced to investigate further, and ethical approval had not been sought to allow retrospective case note review for those who did not attend or dropped out of treatment. Asking prospective study participants to consent to such a review of primary care records may have adversely affected recruitment.

Anecdotal evidence suggests that some people unknown to Doing Well did present to other local programmes, for example the "Choose Life" initiative to reduce the prevalence of suicide, or a "Condition Management" programme run outside the Health Service which was intended to support people with mental and physical health problems to return to work. No assessment was able to be made about the proportion of people who accessed alternative forms of help, nor why they made use of interventions other than Doing Well. Data was not available to assess change in the use of secondary care services.

Of those people who experienced depressive symptoms but were not referred to the service, a proportion would continue to be managed by their general practitioner. One aspiration of the Doing Well programme was that the care received by patients who were not referred to Doing Well would nonetheless be consistent with the Doing Well approach (for example, providing access to self-help materials and encouraging adherence to formulary guidance on antidepressants). In this way, improved depression care could become the responsibility not just of the Doing Well team, but of clinicians in primary care too. However no assessment of this aspiration was able to be made as part of this study.



### 6.3 Strengths of this study

This is an observational study examining a “real life” intervention, including large numbers of patients referred from primary care.

Only five percent of potential subjects were excluded from the study because they did not meet inclusion criteria. This low exclusion rate compares favourably with other similar studies in the UK, as will be discussed in section 6.5.2. Similarly, retention within the study compares favourably with other UK trials, as discussed in the same section.

This study sought to appraise not just the clinical outcomes for individuals, but also to identify any prescribing change that took place in the catchment population served by the Doing Well practices. Using national prescribing data, it was possible to make “before and after” comparisons, and to use geographical controls to compare changes in the catchment and neighbouring areas.

The electronic referral system was implemented successfully, and the “paperless” clinical information system used by Doing Well meant that virtually all the clinical data acquired during treatment was retained by the system and subsequently able to be used for analysis. This was particularly true of PHQ measurements and information about service use (such as number of contacts, and duration of treatment).

The principal outcome measure of this study was changes in rates of prescribing. This information is collated nationally, is accurate and complete, and is independent of the local service.

The successful completion of PHQ scores for almost every patient in this study stands in marked contrast with the poor returns from the other assessment measures. The Work and

Social Adjustment Scale, EQ-5D and Client Satisfaction Questionnaire were all “post-treatment” measures that were not used to inform clinical decision-making, but instead to record the consequences of earlier decisions. In this respect the PHQ can perhaps best be described as a “decision aid”, whereas the other measures in this study were effectively “audit tools”. PHQ completion rates were probably high because staff found it to be a useful way of tracking progress with the patient, and in guiding the choice of intervention that they might require. However some other factors contributed to its near-universal use: the PHQ was an essential component of the referral and electronic note-keeping system, it was quick to complete, readily understood by most patients and easily available in paper and electronic formats without charge.

## 6.4 The evaluation of complex interventions

“Complex interventions” can be broadly defined as “a deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care”.<sup>317</sup> Within the narrower context of clinical trials, the Medical Research Council defines “complex interventions” as trials “that include several interacting components”.<sup>341</sup>

NICE identified 25 interventions that support effective depression care,<sup>26</sup> almost all of which were implemented by "Doing Well " (Figure 6-1). There is therefore some justification for assuming that the implementation of this pragmatic approach is likely to have had a real effect. But since the components of an intervention may act independently or interdependently, it can be difficult to analyse the relationships between them,<sup>318</sup> and a conventional evaluation may struggle to identify individual or combinations of “active ingredients”<sup>342</sup> within such a multifaceted intervention.

Although the Doing Well programme was clearly a “complex intervention”, this study is a description of the intervention, rather than a full evaluation, for the reasons set out in section 6.2.1.

**11 Key Priorities:**

1. Screening in primary care and general hospital settings<sup>1</sup>
2. Watchful waiting
3. Antidepressants in mild depression
4. Guided self-help
5. Short-term psychological treatment
6. Prescription of an SSRI
7. Advice on adverse effects of antidepressants
8. Management of initial presentation of severe depression
9. Maintenance treatment with antidepressants<sup>2</sup>
10. Combined treatment for treatment-resistant depression
11. CBT for recurrent depression

**Other Guidance:**

- Patient preference, information and consent
- Integration of primary and secondary care
- Clear treatment protocols
- Use of telephone support
- Comprehensive assessment
- Alternative treatment options (eg voluntary sector, non-clinical services)
- Suicide risk assessment
- Advice about sleep and exercise
- Psychological interventions (inc CBT & IPT)
- Attention to quality of psychological interventions
- Counselling on beginning pharmacological treatment
- Avoidance of drug treatment for mild depression
- Use of serotonin reuptake inhibitors and generic antidepressants
- Liaison with secondary care about treatment resistance

**Notes**

1. "Doing Well" did not carry out population-based screening for depression, but would systematically assess individuals on the basis of their individual presentations.
2. Although the intervention is designed to be brief, "Doing Well" does advise on continuing treatment.

**Figure 6-1: NICE guidance on management of depression (National Institute for Clinical Excellence 2004)**

Generally speaking, approaches to evaluation seek to answer three broad questions:

1. What are the characteristics of an effective package of interventions?
2. How can the causality of any observed change be assessed and attributed?
3. How should standard trial methodologies be adapted to the issues posed by complex interventions?

Reducing the complexity or variability between groups in a randomised controlled study designs may enhance the accuracy of comparison, but can limit the “real world” applicability of such research. “Context level adaptation” may be required to adjust the intervention to local needs or preferences.<sup>336</sup> For example, the methods section explains that Doing Well treatment protocols did not standardise the type or content of psychotherapeutic interventions provided by the service. Instead, staff were trained and supported to deliver a brief depression-focussed therapy from an accepted modality in a way that met patient needs. The function – appropriate brief therapy – is therefore defined, even though the composition of the consultation is not.

Some have advocated that more attention needs to be paid not just to the outcomes of interventions, but also to the processes by which they become “normalised” and embedded into practice, so that they become workable and integrated “in settings that are themselves dynamic and complex.”<sup>318</sup>

Pawson and Tilley<sup>343</sup> suggest that the efficacy of changed systems emerges as a consequence of the action of stakeholders. The “causal potential” of an initiative therefore “takes the form of providing reasons and resources to enable program participants to change”. This perspective on complexity emphasises the importance of the context in which

change takes place, and the “internal” conditions which may encourage or discourage participants to make and sustain change.

Campbell *et al* suggest that the development of complex interventions can be considered in phases analogous to those used in the trials of new medicines (Table 6-1),<sup>344</sup> and this provides a useful framework to consider the stage of evaluation described here.

Implementing Doing Well required an initial “preclinical” phase to design the intervention on the basis of the relevant evidence. The evaluation reported here probably represents a mix of the “modelling” and “exploratory trial” phases outlined in section 6.4. Future evaluation of Doing Well might require a Phase 2 or Phase 3 study. Evaluation may itself enable the embedding or “normalisation” of a new intervention.<sup>345</sup>

<b>Preclinical</b>	Theory	Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues
<b>Phase 1</b>	Modelling	Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other
<b>Phase 2</b>	Exploratory trial	Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative
<b>Phase 3</b>	Definitive randomised controlled trial	Compare a fully-defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible and adequately controlled in a study with appropriate statistical power
<b>Phase 4</b>	Long-term implementation	Determine whether others can reliably replicated your intervention and results in uncontrolled settings over the long term.

**Table 6-1: Sequential phases of developing randomised controlled trials of complex interventions: from Campbell<sup>344</sup>**

Recognising that there is a balance to be struck between the complexity of “*in vivo*” real world settings and the accuracy of “*in vitro*” randomised controlled clinical trials, the UK Medical Research Council recommended that investigators evaluating complex interventions should:<sup>341</sup>

- Carefully evaluate processes to identify instances where implementation problems (rather than the intervention itself) may have impeded effectiveness
- Use larger sample sizes to take account of the extra variability caused by contextual adaptation
- Use a range of measures rather than identifying a single primary outcome.

## 6.5 Service use

### 6.5.1 *Referral rate of people with depression*

The incidence of depression in the Doing Well area is not known, so the proportion of new cases of depression referred to Doing Well cannot be calculated. However, routinely collated national information (based on Practice Team Information practices) suggests that 4.4% of registered patients aged 15-64 in Scotland consulted a GP, Practice Nurse, District Nurse, or Health Visitor at least once for depression during the year 2005-6.<sup>346</sup> Not all of these cases will have consulted with a “new” depressive episode. Between February and October 2006 (the period of full recruitment to this study), an average of 2.4% of registered patients aged 15-59 in the study practices were referred to Doing Well. It is therefore plausible that just over half of patients experiencing low mood in the community in this area were referred to Doing Well during this time.

This estimate is consistent with epidemiological studies examining the incidence of depression outside the UK (although such studies are scarce, their methodologies diverse and the generalisability of their findings to UK settings may be limited). A systematic review of studies examining the prevalence and incidence of mood disorder published in English between 1980 and 2000<sup>347</sup> found a pooled annual incidence rate of 2.9 cases per 100 population (confidence intervals 1.3 to 4.8). Two subsequent epidemiological studies reported incidence rates of 0.99 per 100 in Canada,<sup>348</sup> and 0.28 per 100 (for men) and 0.41 per 100 (for women) in Sweden.<sup>349</sup> The observed incidence of referrals to Doing Well of 2.4 per 100 therefore falls within the higher range of these international studies.



## 6.5.2 *Access and service use*

### 6.5.2.1 **Access to Doing Well**

Doing Well was designed to be a "low intensity, high capacity" intervention that would provide depression care for a whole population. It was also designed to be convenient for patients to use: waiting times were kept as short as possible, all consultations were in the local GP practice, and the primary care setting and ethos minimised the stigma that can be associated with psychiatric treatments. Psychological and pharmacological approaches were combined in each consultation, since inconvenience in accessing separate medical and psychological services may act as an obstacle to appropriate care.<sup>136</sup>

The "Doing Well" service was used by about twice as many women as men, in keeping with similar trials and population surveys of depression prevalence.<sup>350</sup> It is not known why twice as many women consult with depressive problems than men. It may be that depression is a condition that occurs more frequently than women, that women are more likely to seek help with emotional problems than men, or that depression in men presents differently from women in a way that conventional diagnostic and health care systems do not adequately recognise.<sup>351</sup> Whatever the case, it seems as if the Doing Well response to gender-based differences in depression is no different from conventional care.

There was a significant effect of gender on PHQ outcomes, with women in the Doing Well group showing an average PHQ improvement of 1.36 points greater than men ( $p=0.006$ ). Age groups over 35 years had significantly better outcomes in this study than people in 16-25 year age group ( $p<0.001$ ).

### 6.5.2.1 Deprivation

There is a correlation between income inequality and rates of mental illness,<sup>352,353</sup> and an international study suggests that the prevalence of depression in lower income groups is between 1.5 and two times as frequent as in higher income groups.<sup>1</sup> There are a number of possible reasons for this.

Firstly, low socio-economic status may be a direct cause of depression, or be closely associated with other factors known to increase the prevalence of depression. Such factors include chronic physical health conditions,<sup>354</sup> social exclusion,<sup>355</sup> substance misuse, unemployment, poor built environment<sup>356</sup> and lack of access to green space<sup>357</sup> or recreational facilities.<sup>358</sup>

Secondly, if the experience of depression makes it harder to find or keep a job, “social drift” may account for a greater proportion of people with depression living in areas with cheaper housing. Although anxiety, impulse control disorders and severe mental illness are all strongly correlated with inequality, mood disorders may be less so, especially for men.<sup>359</sup>

Finally, people living in deprived areas may have different patterns of illness recognition and help-seeking behaviour which may influence their ability to respond to the kinds of care that might be offered.

Consultation rates for depression amongst Practice Team Information (PTI) practices in Scotland in 2007-8 were 25 per 1000 males and 50 per 1000 females in the most deprived quintile, compared to 13 per 1000 and 29 per 1000 respectively in the least deprived quintiles.<sup>360</sup> In other words, consultation rates were roughly double in the most compared to the least deprived quintiles.

Some Doing Well practice referral rates were three times higher than others, and we would have anticipated a positive correlation between greater deprivation and higher referral rates. However no such association was found. This would be compatible with a situation in which GPs were referring a lower proportion of patients with depression from more deprived areas.

This may be because GPs were less likely to recognise depressive symptoms in people presenting from more deprived areas, that there were greater rates of primary substance misuse disorders or other problems in this group that made patients ineligible for referral, or because GPs did not believe that the Doing Well intervention would benefit these patients.

It is not known why GPs should refer at such different rates, though such variation is not confined to mental health care. Work from our group suggest that half the variation in antidepressant prescribing rates in Scottish general practices are explained by nine factors, most prominent being deprivation and long-term limiting illness, but also including the age, gender and training of the GP, the location of the practice and the training status of the practice.<sup>21</sup> Given that antidepressant prescribing behaviour will be strongly influenced by rates of detection and diagnosis of depression, it seems likely that the referral rate to Doing Well may be influenced by similar factors. However it was not possible to examine such potential associations in this study.

Once referred to the programme, there was a slight association between deprivation and outcomes when all groups receiving some treatment were analysed together. There was no significant effect for the “treatment complete”, “transfer” and “disengaged” groups when examined independently. It therefore seems likely that any disparity in outcomes between more and less deprived groups is primarily related to factors operating prior to and including the decision to refer.

### 6.5.2.2 Impact on workload in primary and secondary care

Recruitment to the Doing Well programme continued at a relatively stable rate of 1.3 cases per 1,000 population per month throughout the study period. There were no financial or other incentives for general practitioners to recruit or refer to Doing Well, other than the expectation that their patients would receive an appropriate clinical service. In this respect, continuing referral rates acted as a proxy indicator of the usefulness of the service to general practitioners, and thereby suggested that the programme was helpful in a “real world” setting. The programme continued to be resourced by NHS Greater Glasgow and Clyde after funding from the Centre for Change and Innovation ended. At the time of writing in February 2010, Doing Well covered 25 out of 30 practices in Renfrewshire, and is planned to provide a service to all 30 practices by summer 2010.

The impact of "Doing Well" on GP workload was not directly examined in this study, but we note that the programme was initially welcomed by all local GPs, and sustained by participating practices for more than two years.

Some psychiatrists are adamantly opposed to any extension of their involvement to include people with mild symptoms or psychosocial distress rather than identifiable psychiatric disorders. Their opposition is based on a number of concerns, but prominent amongst them is the fear that services open to mild problems in living will be overwhelmed by demand, and so exclude people with more clearly medical disorders (like bipolar disorder and schizophrenia) from accessing a finite mental health resource.<sup>361</sup>

The Doing Well experience suggests that minimal psychiatrist involvement is required to maintain an adequate depression service. The investment by secondary care in other resources in Doing Well may act to protect secondary care services by dealing with mild

problems in a different way. However this study was not designed to assess that possibility directly.

### **6.5.2.3 Duration of treatment**

Doing Well saw patients for an average of 14.6 weeks in total. During that period of time, the mean number of contacts was 5.0 and total treatment contact time was a mean of 151 minutes (median 135 minutes) for the treatment complete group. An average of two and a half hours of clinician contact would be considered to be a “brief intervention”, even though the total duration of contact was nearly four months. It was not possible in this study to distinguish the therapeutic effect of direct “contact time” from that of longer duration of treatment overall (since depression tends to remit over time).

In the Doing Well cohort, almost all the benefit was also seen within three contacts, a similar finding to another UK study which found the greatest symptom reduction arose in those patients who ended treatment after three sessions.<sup>309</sup>

### **6.5.2.4 Retention within the programme of care**

In this study, 78% of eligible patients attended for a least one appointment. Twenty-one percent of eligible patients subsequently disengaged from treatment, meaning that 44% of people completed treatment *per protocol* with a further 13% referred for treatment elsewhere (the “transfer of care” group).

Younger patients and those from areas of increased socio-economic deprivation were less likely to complete treatment in this study. The outcomes for patients who “disengaged” were significantly worse than for those who continued in treatment; this may also be true of those who failed to attend any appointments. Given the difficulties that people with depression may have in accessing treatment because of their condition, this finding requires

further investigation. The lack of response to treatment in the disengaged group was evident early in treatment.

Retention within the programme can also be compared with other work. There was a significant attrition rate between referral and first appointment: 22% of eligible subjects either declined to take part or did not attend any appointment. However, this rate of non-attendance is consistent with a 20% non-attendance rate in psychiatric outpatient settings,<sup>362</sup> and significantly lower than the 39% non-attendance rate observed in one primary care mental health team.<sup>309</sup> Attrition rates in the first six weeks can be up to 50% in naturalistic settings<sup>363</sup> and up to 36% in clinical trials of antidepressant treatments.<sup>364</sup>

These figures can be compared with similar programmes established in Doncaster and Newham as part of the Improving Access to Psychological Therapies (IAPT) programme in the NHS in England,<sup>311,365</sup> and an earlier trial of a primary care mental health team in Leeds, England.<sup>309</sup> The findings from these studies are summarised in Table 6-2.

The Doncaster site was set up to accept GP referrals for patients with depression and a PHQ of 10 or more, and/or of anxiety and a GAD-7 score<sup>257</sup> of at least 10.<sup>365</sup> Eighty-three percent of subjects who met these criteria had a diagnosis of depression. Patients who had experienced “repeated treatment failures” were excluded from the pilot. Of 3,994 patients referred, 57 (1.4%) were considered unsuitable and were not offered an initial appointment. Of the 2,290 patients whose experience could be evaluated, 457 (20%) did not attend or refused a service and 569 (25%) dropped out of treatment. 1178 (51%) patients completed treatment *per protocol*.<sup>311</sup>

A second Improving Access to Psychological Therapies site in Newham, London was set up as a Cognitive Behavioural Therapy service for a range of disorders.<sup>365</sup> The service accepted

self-referrals and referrals from employers, community groups and Job Centre Plus as well as GPs. Staff were all CBT therapists, working between bands 5 and 8 of the NHS pay scale. Only 46% of referrals received were for depression, and this range of non-clinical referrers may explain the high rate of “ineligible” referrals (35%). A majority of subjects (78%) had experienced their symptoms for six months or more. Overall, 154 (36.1%) patients completed treatment, with 15.7% of patients being transferred to other services and 27.9% dropping out of treatment.

Gilbert et al<sup>309</sup> describe a service designed to offer assessment and brief psychological therapy for common mental health problems, principally anxiety and depression. Staffed by “primary care mental health workers” (with a background in social work, counselling, community psychiatric nursing and occupational therapy), the service operated in Leeds in the North of England. 75% of patients had problems with depression. Of 5,539 patients able to be analysed, 214 (3.9%) were considered to be inappropriate for treatment. Overall, 982 (18.4%) of patients completed treatment, with a further 968 (18.2%) being referred for treatment elsewhere.

Site (n=total referrals)	Eligibility (% all referrals ineligible)	Did Not Attend	disenga ged	Transfer of care	Completed treatment per protocol	Completed treatment or transfer of care
Doing Well n=1585	Depression of any severity, including depression with anxiety (5.1%)	22.5%	20.9%	13.0%	43.6%	56.6%
Doncaster <sup>311</sup> n=3994	“Moderate to severe depression or anxiety unless repeated treatment failure” (1.4%)	20.0%	24.8%	n/a	51.4%	51.4%
Newham <sup>365</sup> n=1043	“common mental health conditions” (35.1%)	20.4%	27.9%	15.7%	36.1%	51.8%
Leeds <sup>309</sup> n=5539	“common mental health problems” (3.9%)	41.5%	18.2%	21.9%	18.4%	40.3%

**Table 6-2: comparison of treatment completion rates in UK primary care mental health services. “Ineligible” patients expressed as a percentage of total referrals; other parameters expressed as a percentage of referrals meeting inclusion criteria.**

With the exception of the Newham site, which accepted referrals from a much wider range of sources, and acknowledged difficulties in managing this, each of the programmes had similar rates of “ineligibility”. Although Newham excluded far more people than Doing Well or Doncaster, the proportion of people “completing treatment” (if this is taken to include



transfers to other services as well as treatment within the receiving programme) were generally similar at just over 50%.

This study was unable to establish whether retention in treatment was associated with better outcomes, but it seems plausible that this would be the case- especially if “retention” included being referred on for more specialist services where an initial intervention failed to be effective. If so, measures to improve retention should be associated with better overall outcomes, and could be presumed to be particularly applicable to younger subjects, men rather than women and people coming from areas of socio-economic deprivation.

## 6.6 Clinical outcomes: comparison with similar programmes

The mean change in PHQ after treatment in this study was 10.6, a fall of 62% in the depression score. In this study, 42% of patients entering treatment with a PHQ score of ten or more in the “treatment complete” group had a final PHQ score which could be considered to indicate “remission” (a PHQ of 5 or less) at the point of discharge. Seventy-nine percent of this group showed a “partial remission” with a final PHQ score of less than ten. Such changes represent important clinical improvement, and are similar to those arising from other studies of depression in primary care.

This section compares the "Doing Well" intervention described here with two similar observational studies and two randomised controlled trials that were published after the Doing Well programme started. The observational studies were:

1. the “Doncaster” Improving Access to Psychological Therapies (IAPT) pilot, which was funded by the Improving Access to Psychological Therapies programme in the NHS in England<sup>365</sup>
2. the “Leeds” trial of a primary care mental health service for 54 GP practices in Leeds, England<sup>309</sup>

The Newham Improving Access to Psychological Therapies (IAPT) programme is not discussed here because it did not deal principally with depression and used a different model of therapeutic intervention. The two randomised controlled trials were:

3. The “Northern England” exploratory study of enhanced care for depression in practices in the North of England.<sup>310</sup>
4. The Threshold for Antidepressant Response study<sup>121</sup>

The two observational studies were introduced in Section 6.5.2.4. The Northern England study was a Phase II patient-level randomized controlled trial in primary care, nested within a cluster randomised trial. Subjects were allocated either to a “collaborative care” arm (with case manager-coordinated medication support, brief psychological treatment and enhanced specialist and GP communication) or to usual care. Practices were randomised to provide either the intervention or treatment as usual, and patients in the intervention practices were further randomised to receive either enhanced care or treatment as usual. This “nested” design allowed for practice-level and patient-level effects to be discerned. The study was intended to estimate the effect size of the intervention in order to support the study design for a future “Phase III” trial. Recruitment to this randomised controlled trial was low: 114 patients from a total practice population of 213,360 people.

The Threshold for Antidepressant Response study<sup>121</sup> examined the treatment of mild depression in primary care. Two hundred and twenty patients with a “new” case of mild depression were treated with supportive care from their GP or supportive care plus an SSRI antidepressant. New cases were defined as not having received antidepressant treatment for the previous twelve months, and mild depression was defined as a Hamilton Depression Rating Scale score of 12-19 (roughly equivalent to a Personal Health Questionnaire score of 12-18<sup>366</sup>). Symptoms were required to have been present for at least eight weeks. Follow-up was at 12 and 24 weeks, and used the Hamilton Depression Rating Scale and Beck Depression Inventory to assess change in depression status.

This study sought to investigate “real world” practice in primary care. However only one in ten of patients with a new episode of depression were referred into the study, and only 37% of those referred did participate. One third of observer ratings had become “unblinded” by

26 weeks, and there was some “cross-contamination” of the two arms, with twenty percent of subjects in the “supportive treatment only” group receiving an antidepressant, and thirteen percent of subjects in the “supportive treatment and antidepressant group” who did not actually receive drug treatment.

Table 6-3 summarises the data from Doing Well and the two observational studies. Although no direct comparisons can be made across all parameters, some trends do emerge. Both the Doing Well and the Doncaster programme focussed on depression treatment using a stepped care model that included guided self-help, and both initiatives showed clear similarities in referral rates, age, gender, severity of illness at referral, cost per year, proportion of patients completing treatment per protocol, mean number of contacts, and mean treatment duration.

Although the “Leeds” trial recruited a lower proportion of subjects with depression, and had lower completion rates, the number of contacts is also comparable.

Feature	Doing Well	Doncaster IAPT <sup>311,365</sup>	Leeds <sup>309</sup>
GP referral	100%	96%	97.5%
Diagnosis of depression	100%	83%	75.4%
Study participants	1501		
Total catchment population	76,000	290,000	n/a
Referral rate /1000 total population	15.6	14.2	n/a
Staff WTE per 1,000 pop	0.096	0.011	n/a
Cost £/year (per head/year)	£240,000 £3.16	£1,460,000 £5.03	n/a
% complete treatment or transfer per protocol	57%	51%	40.3%
Duration<6m	100%	26% <sup>1</sup>	n/a
PHQ score>14 at referral	70%	62%	n/a
Mean PHQ at referral	17.0	16.0	n/a
% female	66%	66%	69%
Mean age	37.5	39.0	36.2
Median wait	15 days	21 days	n/a
Mean contacts	5.0	4.9	4.6
Duration of treatment	2.5 hours	2.8 hours	n/a

**Table 6-3: comparison of Doing Well service parameters with comparable UK observational studies. Note 1: mean duration 11 months**

Table 6-4 summarises the change in primary clinical outcome measure for these four UK studies, which show a range of improvement of between 49-63%. The studies use the PHQ, CORE or HADS, so direct comparisons between the outcome measures cannot be made. Differences in recruitment, intervention and duration of treatment and follow-up also mean that the studies are not directly comparable. Doing Well, for example, did not have a lower cut-off for depression severity, whereas the Threshold for Antidepressant Response trial only included patients with an HDRS score of 12-19.

	Before treatment score	After treatment score	% reduction in score	absolute fall
Doing Well (PHQ) “treatment complete”, n= 654	16.73	6.13	63%	10.6
Doncaster (PHQ) <sup>311</sup> “completers”, n=869	15.39	6.31	59%	9.08
Leeds (CORE) <sup>309</sup> Intervention, n=553	17.7	8.8	50%	8.9
Northern England (PHQ) <sup>310</sup> Intervention, n=35	17.51	8.80	50%	8.71
THREAD (HDRS) <sup>121</sup> “SSRI plus supportive care”, n=112	15.45	7.92	49%	7.53

**Table 6-4: change in primary clinical outcomes measures (PHQ or HDRS) for Doing Well and comparable recent UK studies**

The Doing Well and Doncaster studies both used the PHQ and had similar methodologies.

Clinical outcomes in the two services were comparable, with a mean PHQ fall of 9.1 points in the Doncaster cohort (for patients with depression of less than three months duration) similar to the reduction after treatment in "Doing Well" of 10.6 points.

Although no direct comparison can be made between the PHQ and the Clinical Outcomes in Routine Evaluation measure used in the Leeds study, the study used a “clinical score” with a cut off of 11.9 for men and 12.9 for women to distinguish clinical from non-clinical populations. The mean change in scores from 17.7 before to 8.8 after treatment suggests a transition to “non-clinical” status. The equivalent change for Doing Well and Doncaster cohorts was a shift from “moderately severe” depression to “mild” depression.

The “Northern England” trial recruited patients with a similar depression severity at referral, and showed a slightly smaller reduction in PHQ score by the end of treatment.

The Threshold for Antidepressant Response trial found that the antidepressant drug plus supportive treatment group did slightly better than the supportive treatment only group over 26 weeks. But the differences were relatively small, and reduced over the follow-up period: 2.3 HDRS points at 12 weeks and 1.7 HDRS points at 26 weeks. These differences are probably not clinically significant.<sup>121</sup> As the authors acknowledge, the trial was not placebo-controlled, so it is not possible to know whether the small benefit seen in HDRS scores was a specific pharmacologic effect of antidepressant treatment. No significant change was found in the self-completed Beck Depression Inventory scores.

A major American trial was published after the closure of recruitment for the Doing Well study described here. Although not directly comparable to UK work, it is worth describing briefly.

The STAR\*D research programme was a series of randomised controlled trials funded by the US National Institute of Mental Health that aimed to investigate the optimal sequence and combination of depression treatments if initial drug treatment was not successful. Patients were included in the study if they had non-psychotic major depressive disorder, and were suitable for drug treatment as the first step in care. Patients who did not achieve remission or could not tolerate a treatment step progressed to the next step in the treatment protocol.

This “broadly representative group” of 3,671 outpatients in primary and secondary care included those with complex, comorbid, and recurrent depression: two-thirds of patients had at least one concurrent general medical condition, two-thirds had at least one other psychiatric disorder, over half reported a mood disorder in at least one first-degree relative and over half met criteria for anxious features.<sup>136</sup>

An “equipoise stratified randomised design” allowed patients to either switch antidepressant agents or augment their antidepressant with another drug or cognitive therapy. Level two offered four switch and three augmentation options; the latter included cognitive therapy with or without antidepressant treatment. Levels three and four represented specialist medication options, and do not relate to this study. Remission was defined as a reduction to five or less in the Quick Inventory of Depressive Symptomatology–Self-Report scale (QIDS-SR16). Remission was achieved by 36.8% at step one, and by 30.6% at step two. The remission rate at step 1 was higher for those who had not previously been treated for depression compared to those who had received treatment in the past (42.7% vs 35.6%). Longer duration of illness did not of itself influence the likelihood of remission.<sup>367</sup>

The response rate (50% or more symptom reduction from intake) was 49% at step 1, 29% at step 2, 17% at step 3 and 16% at step 4. Overall, about one-half of patients responded in the acute phase of treatment when drop-outs were taken into account.<sup>268</sup> Longer-term data suggests that only about one-half of patients stayed well at one year.<sup>265</sup>

Updated NICE guidance on depression published in 2010<sup>368</sup> reviewed the evidence relating to collaborative care in depression. The guideline recommended that collaborative care should be an important part of the care for people with depression associated with comorbid physical health problems. However the guidance did not recommend the implementation of collaborative care for other groups as part of usual care in the UK. This decision reflected considerable variation in the patient group, type of treatment, intensity of intervention and staff skill mix in the studies considered relevant to the guideline review. Collaborative care was more effective than standard care, but the effect sizes were small. Concordance with antidepressant medicines was enhanced in collaborative care settings. No UK-based studies examining the cost effectiveness of collaborative care were identified,



though it was anticipated that costs would be greater, given the increased resource implicit in the provision of multidisciplinary input to patients. Modest clinical benefit and uncertainty about cost-effectiveness therefore prevented the Guideline Development Group from recommending this form of collaborative care model in the NHS. However the guideline does acknowledge that low-intensity interventions (such as behavioural activation and medication management)<sup>312</sup> may shift the cost-benefit balance. Advocates of this form of service delivery anticipate that low intensity care models may constitute a radical “new paradigm” for future mental health systems.<sup>369</sup>

## 6.7 Prescribing outcomes

### 6.7.1 *Influences on levels of prescribing*

The level of defined daily doses prescribed are influenced by a number of factors,<sup>17</sup> which could be summarised as follows:

#### 1. **The incidence and prevalence of the condition for which the drug is prescribed**

The prevalence of depression in Scotland is not increasing. Antidepressants are commonly prescribed for conditions other than depression, including anxiety, eating disorders, insomnia (tricyclics and related drugs), obsessive-compulsive disorder, post-traumatic stress disorder, neuropathic pain (tricyclics and related drugs), pre-menstrual syndrome (SSRIs) and enuresis (tricyclic drugs). The drug duloxetine has a dual indication for both depression and urinary incontinence.

#### 2. **The consultation and detection rates for that condition**

Consultation rates for depression in primary care in Scotland may be falling. As discussed in the literature review in section 3.2.2, many cases of depression will not be picked up by the GP at a first visit. As discussed in section 1.1.2, the recorded

incidence of depression in Scotland seems to be changing. The reasons for this are not clear, but may relate to the implementation of the Quality Outcomes Framework, to changes in Reid codes for depression, or a reduction in psychosocial distress as suggested by the Scottish Health Survey.

### **3. The decision to prescribe for that condition**

As discussed in section 3.3.4, not all episodes of low mood require antidepressant treatment, and the GP's decision to "medicalise" such an episode by treating with drugs will depend on a range of factors, including the availability of other forms of treatment and the doctor's perception of patient preference

### **4. The dose of drug(s) prescribed**

As discussed in Methods section 4.8.2, Selective Serotonin Reuptake Inhibitor (SSRI) drugs are often prescribed at multiples of daily doses because the "standard" dose in the British National Formulary is equivalent to the DDD. The defined daily doses for tricyclic drugs and venlafaxine are lower than the standard dose, although these drugs are often prescribed far below a standard dose for an antidepressant effect. The dose-response curve for SSRIs is flat, and there is little evidence to support dose increases for other drugs.<sup>370</sup> Nonetheless, routine practice commonly prescribes at higher doses, and dose escalation is a common strategy deployed when patients fail to respond to the standard dose.

### **5. The duration of the course of treatment**

Compliance with antidepressant prescriptions reduces quickly over time, with about 70% of drugs still being taken one month after the prescription, 30 to 50% of drugs still being taken three months after the prescription, and only 20% of patients still compliant with medicines six months after the prescription was first issued.<sup>110,118,156</sup>

Recent evidence suggests that most of the increase in Defined Daily Doses in recent

years can be attributed to longer treatment in a minority of patients, rather than an increase in the numbers of people taking these drugs.<sup>110</sup>

### *6.7.2 Mechanism of Doing Well prescribing change*

Doing Well had an explicit remit to encourage “rational” prescribing, and this took two principal forms. Firstly, prescribers were asked to comply with formulary antidepressant drugs unless there were clear contra-indications to their use. Secondly, doctors were encouraged to limit prescribing for people with “mild” depression: not to use drug treatment first-line for patients with a PHQ of less than 15, and to “watchfully wait” before prescribing for patients with a PHQ of 16-20.

Monitoring prescriptions made for Doing Well patients suggests that antidepressants were used in relation to the severity of depression, in keeping with NICE guidance. Similar results were reported following the introduction of the Hospital Anxiety and Depression scale into routine practice in primary care in Southampton.<sup>40</sup>

Doing Well practices had a lower rate of rise of antidepressants compared with neighbouring areas and the Scottish national trend. Doing Well practices, however, did not differ from other practices in Renfrewshire (the “non-Doing Well” group) with regard to the reduction in cost of antidepressants. The significant additional cost reductions seen in Renfrewshire practices compared to those in Inverclyde and Scotland would largely be accounted for by an increase in formulary-compliant prescribing.

This information suggests that GPs may respond to guidance and support to change what they prescribe, but that they are unlikely to change how much they prescribe unless they are able to access a service that provides an alternative to drug treatment.

Improved formulary compliance will reduce prescribing costs, since the formulary drugs were cheaper than almost all other non-formulary items. But guidance on when to prescribe could have resulted in an overall increase or decrease in antidepressant use. Firstly, general practitioners in Scotland may not have been using antidepressants inappropriately for people with mild depression,<sup>205</sup> but may have been under-detecting and under-treating people with more severe depression. In that situation, “rational” prescribing practice would have resulted in an increase in the Defined Daily Doses of antidepressants used. Secondly, there is some evidence that quality improvement programmes for depression care increase compliance with medicines,<sup>113</sup> and this may have led to an appropriate increase in the duration of drug treatment.

These possible interacting influences on antidepressant prescribing are set out in Table 6-5.

factor	possible Doing Well effect	rationale	Likely influence on DDDs
Detection of new cases of depression	more detection	Increased GP and public awareness of depression as a local health issue	increase
Referral of new cases for specialist support	more referral	Prompt access to depression service which patients and GPs seemed to find acceptable/helpful; less reliance on drugs alone to manage depression	reduce
Decision to prescribe	more rational	GPs encouraged not to prescribe for a PHQ score <15, but to consider antidepressants for higher scores	reduce or increase
Prescribing-dosing	better adherence to formulary guidance on dosing	Formulary recommended using standard doses of antidepressants, a message strongly endorsed by Doing Well. If mainly tricyclics, it would mainly increase; if SSRIs probably decrease	reduce or increase
Prescribing-duration	better adherence to formulary guidance on duration	Individual work with all patients to stress importance of continuing drug treatment	increase

**Table 6-5: possible mechanisms of Doing Well influence on prescribing practice**

The effect of the Doing Well programme on prescribing change was statistically significant but clinically modest. This may be because the most important factor in DDD usage is the consumption of antidepressants by patients with long-term illness. Recently published UK data found that 78% of all antidepressant prescriptions were for less than 30 days.<sup>110</sup> If this proportion were correct, then any influence on prescribing for a new episode will be diluted by the large majority of patients who discontinue medicines within a few weeks anyway. In addition, a short-term intervention like Doing Well would have relatively little influence on the minority of patients who did take long-term antidepressants. Nonetheless, it may be that a reduced incidence of new scripts will slowly act over time to reduce the level of long-term antidepressant use.

Possible influences on GP behaviour were set out above, but as sections 3.3.4 and 3.7.1.1 of the Literature Review describe, prescribing decisions are complex, and influencing clinical behaviour is usually difficult. Although it was not possible in this study to investigate which aspects of Doing Well did or did not influence prescribers, the following characteristics of the programme are consistent with the principles of successful “change programmes” reviewed in section 3.7.1.1. Doing Well was established in collaboration with local GPs and sought to respond to their feedback and comments. It offered a simple and plausible way to manage depression care, which was consistent with published guidance (such as the NICE guidance) and local formulary recommendations. It may be that some of the “marketing” approaches taken to promote local formulary usage did influence the choice of antidepressant drug.

## 6.8 Service responses to clinical uncertainty

The Doing Well intervention was conceived and delivered as part of the Scottish Government's strategy to improve care for people with depression. Doing Well was therefore not established to question or re-examine fundamental aspects of depression, but instead to develop a pragmatic programme of care.

Nonetheless, some of the assumptions that underpin conventional depression care are open to question. These assumptions generally hold true, at least for many people for most of the time. But they are simplifications of the “real life” situation in which clinicians find themselves, and it might be appropriate here to make them explicit. The assumptions could be summarised as follows:

- that depression is a recognisable clinical entity that is identifiable by trained clinicians
- that the appropriate threshold, intensity and duration for delivering both antidepressant medicines and psychological therapies can be determined for individual patients
- that assessment of symptoms and clinical outcomes will guide service delivery

Rather than gloss over these simplifications, Doing Well aspired to acknowledge and “work through” such assumptions rather than avoiding them. These issues are discussed in the following sections.

### 6.8.1.1 Managing clinical depression, sadness and distress

As described in section 3.2.1 of the literature review, the authors of NICE guidance on depression came to a view that depression “is too broad and heterogeneous a category, and

has limited validity as a basis for effective treatment plans".<sup>26</sup> Fundamental to this diagnostic uncertainty is the ability to distinguish between depressive illness and "normal" sadness:

"the very success of the DSM and its descriptive criteria at a practical level has allowed the field of psychiatry to ignore some basic conceptual issues that had been lacking at the foundation of the DSM enterprise, especially the question of how to distinguish disorder from normal suffering"<sup>43</sup>

Unless this distinction can be made, the concept of depression may come to "engulf all the problems that life poses".<sup>43</sup> Low mood or stress undoubtedly causes much population distress, but how much of this is attributable to a medical condition? How much remits without treatment? Which people are likely to benefit from treatment? The broad definition of depression used by Doing Well meant that GPs were not required to make judgements about who should or should not be "medicalised" and referred for specialist help.

Rather than seek to separate patients into distinct categories of either illness or distress based on diagnostic criteria, Doing Well worked to a loose definition of affective problems, accepting for assessment and treatment anyone that GPs felt had "low mood, depression or adjustment disorder". Although access to the service required a medical referral including a PHQ score, there was no "severity cut-off" that determined whether so-called mild, moderate or severe depression would be accepted by the team.

This approach reduced the risk of people with so-called "mild" disorder being excluded from care. In doing so, it opened up the possibility of a mental health service accepting responsibility for people who would not be considered "ill" in a conventional clinical sense. This change introduced two potential problems. Firstly, Doing Well had to be confident that the team had the skills to be able to help people with emotional problems, even if these did

not conform to a clinical diagnosis. Secondly, the service as a whole needed to have the capacity to deal with the large numbers of people with “mild” mental health problems in the community.

Since most mild low mood will remit spontaneously over relatively brief periods of time, the service design also needed to ensure that professional involvement did not impede or complicate a recovery that might have taken place without professional help. NICE guidance suggests that guided self-help is an effective response to mild depression.<sup>26</sup> Provision of this service in *Doing Well* used non-clinical staff and encouraged engagement and responsibility on the part of patients. This low intensity approach was relatively “non-clinical”, and probably reduced the likelihood of unproductive contact with secondary care mental health services.

#### **6.8.1.2 Making decisions about the type and intensity of treatment**

Even if the of qualitative assessment of thoughts, feelings and behaviours could be accurately translated into a numbered score, depression care differs fundamentally from other types of chronic disease management. “Stepped care” implies that the complexity and intensity of treatment increases in proportion to the severity of the condition, but this assumption is open to question for depression.

People with severe “biological” depression may respond very well to drug treatment, requiring relatively little additional support or therapy. “Mild” depression, on the other hand, is the traditional province of long-term psychotherapy. Psychotherapies of this kind may require highly skilled practitioners to implement treatment over several months or years. For some people, therefore, the intensity, complexity and duration of treatment may be greater with a low PHQ than with a high one. This inversion of the “stepped care”



assumptions for at least some people calls into question the validity of the model for depression in general.

Unfortunately, there is little evidence available at present to answer some of the uncertainties encountered by services such as Doing Well. For example, although people exposed to brief psychological interventions seem to do better than waiting list controls (as discussed in section 3.4.2.3 of the Literature Review), we do not know whether this applies to all patients, nor how the long-term outcomes of people receiving brief therapy compared with those receiving longer treatments.

This issue is relevant for service managers (because conventional psychotherapies are so resource-intensive), but also for our wider public health (since the prevalence of depression is so high). Which provides the greater benefit: prompt access to a “good enough” brief treatment for all who need it, or a long wait for a “gold standard” treatment for a minority of people with depression? We cannot answer this question without longer-term follow up studies with a full health economic assessment. However the Doing Well intervention (and the results from a similar service in Doncaster, as described earlier in this chapter) does suggest that it is feasible to integrate a “low intensity, high capacity” model of care for depression into conventional primary and secondary care services.

More work requires to be done to optimise some operational characteristics of such “low intensity” models. For example, what mix of face-to-face, telephone or email contact is most appropriate? What type, level and mix of skills are needed to make a staff team most clinically effective? How can we better identify patients for whom “watchful waiting” – which represents a kind of therapeutic containment – would be more appropriate than a usual clinical intervention? To what extent are interventions “done to” patients, and to what extent do they enable people to manage their own recovery over time?

### 6.8.1.3 Assessing symptoms and outcomes in practice

The PHQ became the central feature of care delivery within the Doing Well system.

Although there was no "PHQ threshold" for a referral to the service, once that referral had been made, the PHQ was used to define or guide treatment at several points in care. This approach had its limitations, as described earlier in section 3.6.2.4.

There are significant differences between the various depression scoring tools available, which differ in sensitivity, specificity and inter-rater reliability. In a recent direct comparison of the PHQ and the Hospital Anxiety and Depression Scale (HADS) scores in a study set in Scottish Primary care, Cameron *et al*<sup>259</sup> suggest that the PHQ may overestimate the prevalence of major depression, and this is consistent with two other comparison studies.<sup>371,372</sup> There is no doubt that a PHQ score is not directly equivalent to a HADS score, and the "pragmatic" cut-off points described by Kroenke<sup>253</sup> may be inaccurate, as the author himself acknowledged.

All depression scoring systems share some limitations, but the PHQ is at least as accurate as the other systems in common use, and significantly better than physician judgement alone.<sup>372</sup> These uncertainties can be managed in practice, since the PHQ is only one of several factors that were used to guide care. Patient preference, previous response to antidepressants, family history of depression or other mental illness, and the developmental history of the patient all had an important bearing on clinical decisions in relation to appropriate treatment.

The PHQ also proved to be useful as clinical "shorthand" that could express symptom severity in a simple number, rather than having to describe each symptom in detail.

Although it is difficult to evaluate this objectively, there was a clear sense from the team

that the PHQ did form part of a new "shared language" around depression that facilitated communication between the patient and primary and secondary care. The use of the PHQ probably also gave staff some confidence that their own clinical opinion about a patient's progress was referenced in a relatively objective way, and could be used to independently corroborate their actions.

#### **6.8.1.4 Monitoring clinical activity**

An assessment that has been "operationalised" in order to be applicable to a range of people in a population will lose significant contextual and other information compared with an individual assessment. There is a tension between a "generalisable but reductionist" model, and the more complete traditional formulation which has to be developed anew for each individual.

Similarly, rigid adherence to a "system" of treatment may adversely care:

"Effective clinical decision making requires a holistic approach that accepts unpredictability and builds on subtle emergent forces within the overall system... complexity theory saves both clinician and patient from a futile quest for certainty and upholds the use of intuition and personal experience when general scientific rules are to be applied to the individual in context."<sup>373</sup>

But there are also risks in implementing a system that is inadequately controlled. Care programmes that do not manage idiosyncratic practice or place some limits on variation from protocols may provide inappropriate treatment. It has been estimated that 30%–40% of patients do not receive treatments of proven effectiveness, and 20%–25% of patients receive unnecessary or potentially harmful care.<sup>374</sup>

Implementing new systems requires some thought to be given to the detail in which the operational instructions for following the new approach should be described. New systems of care may then choose to check the "fidelity" to the model by tracking various process outcomes.

For example, assessments of cognitive behavioural therapy for depression would typically specify the number of treatments, the grade of therapist, the outcome measures and also have some mechanism by which the content of the consultation itself could be monitored. A view was taken before the implementation of Doing Well that this degree of specification would be difficult to implement in routine practice, and also might diminish the effectiveness of the intervention, if it limited the therapeutic options available to clinicians within the team.

It was therefore decided that tracking a small number of outcome and process measures would adequately monitor the quality of care provided to patients. Clinical progress was assessed by the PHQ, and a range of process measures were routinely reviewed (for example, waiting time to first assessment and the number and duration of clinical contacts). There was no more intrusive examination of the therapeutic modality or content of clinical sessions.

Tracking clinical performance in this way devolved considerable responsibility and autonomy to individual practitioners. This presents a significant opportunity, if it were to allow committed, well-trained staff to individualise care according to their assessment of patient needs. But it also presents some risks, in that less control over treatment might permit inappropriate or ineffective interventions.

### *6.8.2 Staff development and support*

Doing Well clinicians were expected to be able to practise effectively with a significant level of autonomy. The skills, commitment and personal factors that staff brought to their work at Doing Well will have had a significant influence on the outcomes of the programme. To make this work, Doing Well actively supported continuing development of professional skills, the airing of uncertainty or errors in a group setting, and a system of care that fostered both quality and safety in practice.

The staff training budget for members of the community mental health services where Doing Well is sited was about £30 per annum per staff member. The direct expenditure by Doing Well on staff training during the period covered by this study was about ten times that sum.

Examples of professional training were described in the methods section (4.9.1). Quarterly meetings for all "Doing Well" staff were held away from base in order to review performance data and review or formulate protocols and standards for the clinical service.

As described in section 4.6, roughly one day each week was given over to professional development. This policy was initially implemented because of concern to avoid over-burdening staff with excessive direct "one to one" clinical contact with patients. It was felt that clinicians were unlikely to remain effective if they had to spend more than five or six sessions (20 to 24 hours per week) directly treating patients. Since group supervision and administration would not take up more than a further eight hours per week, there was a need to find some other form of productive activity for the remaining hours.

Allocating time to professional development therefore emerged from a practical need to limit the risk of burn-out. However, in retrospect this policy had a number of additional

benefits, some direct and others indirect. The most obvious benefit was the direct improvement in staff skills that were achieved at relatively low cost.

In terms of indirect benefits, the policy seemed to support low sickness absence rates, which may be a proxy indicator for workplace stress or burn-out. Investing in skills and development also conveyed an important message to staff that their views, attitudes and skills were valued by the organisation.

Another consequence of a relatively broad approach to continuing professional development was that staff would bring into their daily practice a range of approaches and techniques acquired during this learning. As described above, the Doing Well ethos was to be relatively "permissive", in the sense of trusting clinicians' professional judgement about what approaches were relevant and safe.

## 6.9 Clinicians and service change

Clinicians know how difficult it can be to bring about behavioural change in individuals, but the support needed to bring about effective clinical behavioural change in staff is less well recognised. Changing practice is almost always difficult, and “educational” interventions to enhance care by GPs, or to improve information available to patients have generally been ineffective. The challenge for Doing Well and other forms of system redesign is therefore not only to ensure clinicians can be effective during individual consultations, but also to rationalise and coordinate the “health system” in order to support that clinical interaction.

Managers and clinical leaders need to develop new ideas about how work should be done, how relationships are managed, and how patients can be engaged to participate in their care. System-level change typically requires coordinated change in a number of areas simultaneously,<sup>375</sup> and the organisational and technical processes of delivering such changes merit attention and evaluation in their own right.<sup>318</sup>

Heifetz<sup>376</sup> defines three types of change situations: “technical” change (Type I) represents situations where the problems are well defined, their solutions are known and those with adequate expertise and time can implement the solution. By contrast, in an “adaptive” situation (Type III), the actual nature of the problem is often less clear and the solution is either not clear or requires people to change their attitudes, beliefs or behaviours. Heifetz proposes an intermediate (Type II) situation, in which there are both technical and adaptive changes to be made.

Table 6-6 sets out some examples of challenges facing the Doing Well programme according to this framework. As anticipated, “Type I” changes were generally easier to implement and monitor than “type III” changes. It was relatively straightforward, for example, to train staff

in the use of the PHQ and then to implement information systems that required it to be recorded for each clinical contact.

Key issues	Problem Definition	Solution and Implementation	Change Type
Uncertainty about the assessment of depression severity	Staff inconsistent or inaccurate in their assessment of depression severity, even though this is critical to the function of the service	Implement system whereby PHQ is used to rate depression severity and to guide treatment decisions	Type I Technical
Insufficient capacity to provide long-term psychological therapy for all patients	Although longer-term psychological therapy is needed by some patients, many will respond to briefer and less intensive treatments (like CBT)	Use PHQ to identify “mild” depression. Implement “stepped care” system that evaluates response to treatment and increases intensity of intervention for non-responders	Type II Technical and Adaptive
Lack of clarity around definition of depression	Depression is too broad a term to be useful as a diagnostic concept – though not everyone agrees with this. Current definition incorporates both normal loss responses and maladaptive responses – though not everyone agrees this is problematic.	Not clear; may be supported by use of PHQ in association with a “holistic” assessment by suitably trained practitioners	Type III Adaptive

**Table 6-6: challenges faced in the development of Doing Well according to the Heifetz model**

It was not possible to manage “adaptive” changes in this way. As mentioned in the previous section, clinical complexity requires staff to respond flexibly to each individual situation. This represents “distributed” clinical responsibility that is consistent with General Medical Council guidance on working within multi-disciplinary teams.<sup>377</sup> Since it is not possible in practice (and probably not desirable in principle) to operationalise or directly monitor



everything that staff do, Doing Well had to find different ways of ensuring adequate quality, as discussed in previous sections.

This success of the Doing Well intervention therefore depended in part upon a shared sense of cooperation and accountability which may represent a form of “distributed leadership”,<sup>378</sup> in which leadership tasks can be collectively performed across a range of individuals. This concept is backed by the research by Denis *et al*,<sup>379</sup> who argues that major substantive change is rarely led by one person, requiring instead collective leadership. They refer to the concept of a “leadership constellation” where members play a distinct role and work together harmoniously.

#### **6.9.1.1 The effect of a new project**

The Doing Well programme was supported by national funding that sought to promote innovation. Staff recruited to the team knew that they were required to make improvements over the care that had been provided historically in that area, and over standard care in other parts of the country. This generated a tone and culture that was characterised by enthusiasm, optimism and commitment.

Like similar projects in the early stages of their development, Doing Well became quite distinct from other teams providing “treatment as usual”. The interpretation of the outcomes of the study therefore require to be conducted with some caution, since well-established programmes, programmes without “special” funding, or programmes that cannot pick and choose the staff that they recruit are likely to have more difficulty in achieving the same outcomes.

Such team positive or “special” team dynamics have been recognised to be important. A sense of being in the forefront of progressive change can often be powerful motivators for

staff and have a positive influence on clinical outcomes. However, such advantages may dissipate quickly when leaders move on, funding ceases, or the projects themselves become mainstream and so less "special".

It is difficult for services to gain insight into their own behaviour in this regard, not least when the author of this evaluation is the same clinical leader whose behaviour might be subject to evaluation. An impartial observer might suggest that anyone naming a new service "Doing Well" is not well-placed to make an independent assessment.

## 7. Conclusions and recommendations

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This evaluation suggests that it is feasible for a relatively small staff team to deliver depression care with appropriate outcomes, yet also has the capacity to see large numbers of patients. The Doing Well approach was grounded in psychological therapies, and based in primary care. The rate of increase of defined daily doses of antidepressants was lower than that in areas which did not implement a Doing Well model of care. Doing Well and neighbouring practices achieved greater cost reductions than comparison areas. These prescribing changes seem to be compatible with “rational” prescribing practice.

The observational design and lack of economic analysis preclude a formal comparison with usual services. Nonetheless it is likely that the Doing Well approach provided modest, incremental improvements over usual care. The implementation of Doing Well required significant changes in four areas of service delivery.

Firstly, Doing Well represented a substantial service reorganisation. This was a complex intervention, implementing a number of changes simultaneously. It was also an “integrating” intervention, making sense of a range of existing therapeutic options, including self-help, pharmacotherapy and psychotherapy. Secondary care expertise was deployed in primary care, and “service delivery systems” were developed to minimise waits and waste.

Secondly, the redesigned system sought to make better use of information. The Personal Health Questionnaire was recorded electronically at every contact, and was routinely used to guide care, monitor outcomes and distribute work within the team. It became useful “shorthand” for talking about depression severity and was widely used in discussions between GPs, mental health workers and patients.

Thirdly, Doing Well provided a psychological approach to care (guided self-help) as the default intervention for all patients, supplemented by antidepressants or more intensive psychotherapies where required. The emphasis on prompt (though brief) psychological intervention inverts traditional practice, which tends to lead with drug treatment or to refer a small proportion of patients to specialists for relatively lengthy and sophisticated psychological treatment.

Finally, Doing Well invested in staff training and wellbeing so as to support effective clinical engagement with patients. Staff encouraged patient choice and participation in the decisions about treatment. Feedback from staff suggested that they valued feeling autonomous, respected, confident and supported in their work. It seems likely that this sense of confidence and optimism shared between staff and patients was an important aspect of the therapeutic relationship, but investigation of this relationship was beyond the scope of this project.

These four changes were all the consequence of deliberate service redesign, in keeping with the original objectives of the “Doing Well by People with Depression” programme proposal. However Doing Well was also designed to be able to reflect and respond to the information gathered by the programme and the feedback provided by patients. The clearest example of this reflexivity is perhaps the way in which Doing Well became formally subject to health policy changes (Integrated Care Pathways<sup>250</sup> and the HEAT target<sup>380</sup>) that the Doing Well programme and staff had helped to inform. More detail about this involvement in policy is set out in section 9.2.

Although not an explicit part of the initial programme design, it seems in retrospect that one of the most important functions of Doing Well was to be able to “contain” distress without necessarily having to “treat” it. The service responded relatively promptly to people who

requested help from their GPs, and came to place great emphasis on the supportive nature of the first long consultation. Many people achieved full remission within three such contacts, and many others were clearly on such a recovering trajectory that they were discharged from the programme before fully well. In this way, Doing Well allowed for (and perhaps encouraged) the “spontaneous” recovery that naturalistic studies suggest happen to many primary care patients without treatment.

This evaluation was not designed to investigate which elements of the Doing Well approach most enabled this recovery. Any study would probably find it difficult to disentangle what might be considered the active components of insight-oriented therapy from a more generic sense of distress being “contained” in a helpful way. Randomised controlled trials would be expected to show a large placebo effect, but “placebo” is an unhelpfully vague term for the critical mix of non-specific service elements that seems to influence recovery so positively.

Patients who had this experience would typically have met with a therapist within two or three weeks of referral, have reached a shared understanding of their problems within the first or second visit, and have received enough support or therapy to be able to leave the programme by a third or fourth visit. People who had not improved at that point would be seen by a psychiatrist or psychotherapist and either treated more intensively within the programme, or transferred on for specialist care elsewhere.

At the point of discharge, a Doing Well patient might have had a better understanding of the causes of their problems, some thoughts about how to prevent or respond to another episode in future, and known that they had access (by telephone or email request) to their Doing Well clinician in future should they request it.

While this evaluation could not measure whether these changes represented improvements over standard care, they do seem like sensible indicators of a quality experience. Without access to the Doing Well service, some of these patients may have received antidepressant drugs they did not need, or waited up to twelve months to see a psychologist or other secondary care staff.

The PHQ may be able to measure “severity” of symptoms, but it cannot distinguish depression from “normal distress”, nor predict whether drug- or talking-based treatments are more likely to be effective. By complementing the PHQ with an hour-long, psychologically-aware initial assessment, Doing Well enhanced the potential to allocate patients to the right mix of care. A skilled, psychologically-oriented formulation can be developed with the patient at a first visit.

Sometimes it is clear from that first appointment that longer-term support will be needed (for example, for people with problems relating to a history of childhood abuse). Often, however, it is not: as discussed in the literature review, the cross-sectional symptom profile of depression, adjustment disorder and acute distress are often identical. The most effective way to distinguish between them may be to observe the patient over a period of time. Similarly, the best way to establish whether a patient is likely to respond to brief therapy is simply to try it and monitor the response. In other words, symptom duration as well as severity is important in adjusting treatment to meet patients’ needs.

The incorporation of “time” into stepped care models is therefore an under-recognised aspect of their benefit. “Containing” distress in a supportive way allows this “watchful waiting” to take place without disadvantaging the patient.

## 7.1 Recommendations

A range of innovations in depression care have been implemented in Western countries in the last decade or so. The main themes in recent research have been the implementation and assessment of "stepped" care models, and the design of "low intensity cognitive behavioural therapies", mainly based in primary care.

Randomised controlled trials of the Doing Well and other "low intensity, high capacity" models of care are needed to better understand the generalisability of this type of intervention in a British NHS context. Such trials would be powered to establish whether outcomes are different compared with standard care, but should also seek to identify the critical elements within a "complex intervention" of this type. It is not known which the most effective elements are, how the various interventions interact with one another, nor what the "cost-benefit" relationship for each intervention is.

For example, some interventions have used relatively unqualified caseworkers to provide telephone support or face-to-face guided self-help; other studies have used much more experienced staff to supervise or deliver treatment. Both approaches have been shown to be effective, even though their deployment of therapeutic skills is very different. Formal comparison of these two approaches would be worthwhile.

Future research in this area should consider extending investigation of depression to include depression and anxiety, since these conditions are so commonly comorbid

It would be helpful to try to identify packages of care that best meet the needs of particular patient groups. For example, would some people benefit more from group, rather than individual therapy? Can we use demographic and other information acquired early in the referral process to understand the likely response to treatment, and design care pathways

better to meet those needs? We know that the prevalence of depression is twice as high in women compared to men, but we manage depression in both genders in more or less the same way. Is this appropriate? How can we improve outcomes for people living in more deprived areas, particularly to reduce the rates of drop-out from treatment?

We need to know more about the long-term outcomes for people treated with brief interventions. Was there any change in the duration of symptoms, or the risk of recurrence in future? This would require a long-term cohort study.

Three particular aspects of future trials would be beneficial. Firstly, an economic analysis would help to understand not only the direct cost of treatment, but also the broader social costs of depression, and their response to treatment. Secondly, it would be helpful to know more about how GPs perceived their access to interventions such as Doing Well, and in particular to measure the impact of such services on the workload in primary care. Thirdly, the natural history of untreated depression is poorly understood, and outcomes of depression treatment in primary care have not been systematically assessed in routine practice. The advent of depression outcome measures as part of the Quality Outcome Framework in primary care offers an opportunity to examine the response to treatment for large numbers of people.

The public health impact of depression is so large that service models to improve depression care should consider interventions that integrate more closely with resources directly targeted at the general public. Measures to reduce the stigma of mental illness, to educate the public about the causes of mental health problems and their treatment, and interventions that provide “direct access” help (such as online self-help, or telephone-based therapies) should be considered.



## 8. Reflections

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*"All who drink of this remedy recover in a short time, except those whom it does not help, who all die. Therefore, it is obvious that it fails only in incurable cases."*

Galen, quoted in Leber<sup>381</sup>

Depression is a common and protean problem that is experienced by most people as a relatively brief, if recurrent condition. For others, it is a chronic, "treatment resistant" condition. The challenge to clinicians and health systems is to be able to distinguish between a "chronic disease" and an illness that has not yet received the right treatment.

While our understanding of the causes of depression and the most effective treatments may be improving, much remains unknown. Given this partial state of knowledge, we cannot prospectively define what the "right" treatment would be for any individual. Perhaps the best health services can do is to aspire to a system whereby "standard" pharmacological and psychological treatments are adjusted in response to patient feedback until depression remits, or care for that person can be shown to have been optimised.

This approach requires access to the relevant information, investigations and treatments. But it also critically depends upon disparate networks of clinicians responding appropriately. Managing the human aspect of this change is perhaps the most difficult. However, clinicians are most likely to choose to modify what they do if they are presented with alternatives that are relevant, understandable, motivating or fulfilling in some way. This is particularly true where the alternatives are easier to accomplish than "standard" care.

The following list outlines some approaches to improving the system response to depression (gleaned from complex systems theory,<sup>283</sup> lean approaches to management<sup>382</sup> and personal reflections about the Doing Well programme). Systems that aspire to make effective changes should:

1. **Make the problem clear**

For example, by using the PHQ as an objective outcome measure to clarify the “symptom count” in depression and so support clinical decision making. This works best when used at every visit as part of routine care, and where the scores are understood by patients, GPs and specialists alike. Note that these measures are most closely aligned to prescribing decisions, since they do not ask “psychologically informed” questions.

2. **Make sure the whole system is captured**

Systems must be developed in partnership with primary and secondary care, integrating services across traditional boundaries. For depression, secondary care expertise will typically be deployed into primary care practices. Such changes should be considered as complex interventions that require to link to, and make sense of, a range of therapeutic options: from self-help and community-based support to pharmacotherapy and tertiary-level specialist services. Changes required are often best implemented simultaneously, since each should reinforce the others.

3. **Design a system that “flows downhill”**

Most importantly, changed systems have to be easier to use than the ones they replace. Otherwise they will require constant effort to maintain the new approach. For example, an emphasis on prompt, though brief, psychological therapy (based on guided self-help) for all who can benefit is more likely to be used than one that only

offers delayed access to therapy, even if this might be more comprehensive or intensive.

#### **4. Use information to guide decisions**

Access to information is a fundamental requirement for both clinical treatment and service development. Staff and patients need outcome measures to adjust treatment in the light of response. The service delivery system needs to use process measures (wait times, caseloads, treatment duration, antidepressant use) to respond appropriately to demand.

#### **5. Identify and eliminate waste and duplication throughout the system**

Service delivery systems need to be refined so that they became not only efficient, but also accessible and easy to use for both clinicians and patients. Multiple referrals, handovers and assessments should be avoided.

#### **6. Ensure minimum effective doses of therapy and antidepressants are used**

This is an obvious statement for antidepressants, where prescribers are keenly aware that the dose-response curve may be flat, while the dose-adverse effects line continues to rise. But this is not so obvious for psychological therapies, where the outcome of the duration and intensity of treatment is less clear-cut. While a prolonged dose of therapy is unlikely to harm a patient, it will harm others if it prevents them from being able to access services.

Most of clinical workload for psychological therapies is defined not by the number of new referrals, but the number of sessions spent treating the people already in care. Unless we can be sure that eight sessions of treatment will be better than four (or even four better than two), we should provide fewer sessions and reinvest the

capacity this releases to maintain spread in helping more

**7. Treat staff as we would expect them to respond to patients**

With respect, generosity and interest. This means investing in training, and avoiding excessive hours of direct patient contact.

## 9. Postscript

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### 9.1 Output

The Doing Well intervention described in this thesis has also been the subject of the following presentations, publications and awards.

#### *9.1.1 Presentations*

The evaluation set out in this thesis informed presentations by the author and/or other members of the Doing Well clinical team at the following conferences and academic meetings:

- Royal College of Psychiatrists Annual Meeting (2006 & 2007)
- British Medical Journal Quality Improvement in Healthcare (2006 & 2007)
- European Association for Behavioural and Cognitive Therapies (2006 & 2007; paper accepted for 2009 but withdrawn by the author since unable to attend)
- British Association for Behavioural and Cognitive Psychotherapy (2006 & 2008)
- Scottish School of Primary Care, SSPC (2006)
- WPA Thematic Conference on Depression and Relevant Psychiatric Conditions in Primary Care (2008)
- European Congress of Psychiatry (2008)
- Paper accepted for European Psychiatric Association Annual Meeting in 2010 but withdrawn by the author since unable to attend.

### 9.1.2 Publications

The following publications directly relating to the Doing Well programme were accepted for publication or in press at the time of writing in February 2010:

Practical Service Redesign: Helping GPs to Enhance Depression Care. Smith,M (2010)  
Chapter in The Oxford Guide to Low Intensity CBT Interventions, Oxford University  
Press, Eds Bennett-Levy,J., Richards,D., Farrand,P., Christensen,H., Griffiths,K.,  
Kavanagh,D., Klein,B., Lau,M., Proudfoot,J., Ritterband,L., White,J., Williams,C.<sup>383</sup>

“Doing Well”: service use and clinical outcomes of a complex intervention to  
improve depression care. Smith,M., Ackland,L., O’Loughlin,S., Young,D., Pelosi,T.,  
Morrison,J. (2010) Primary Health Care Research & Development.<sup>384</sup>

### 9.1.3 Other

The "Doing Well" team was awarded the NICE/Health Service Journal award for “Best  
Implementation of NICE Guidance” across all UK healthcare sectors in October 2006.

Doing Well was shortlisted for a “Shared Learning Award” from NICE in 2007, and is  
published on the NICE website as an example of shared learning in “Implementation Policy”.

The Doing Well service was visited by Tom McCabe, Deputy Minister for Health and  
Community Care in the Scottish Government in November 2004, and by Andrew Robertson,  
Chairman of NHS Greater Glasgow and Clyde in January 2010. The author was asked to  
present the outcomes of the Renfrewshire Doing Well programme to a delegation of World

Health Organisation officials visiting Scotland in October 2007, and to Shona Robison, then Minister for Health in the Scottish Government, in December 2007.

## 9.2 Influence on Policy

The Doing Well intervention described here was initially the product of national policy and Government funding. The findings from this programme and other areas in the “Doing Well by People with Depression” initiative have influenced the development of subsequent work on depression in the NHS in Scotland.

### 9.2.1 *Integrated Care Pathway for Depression*

The investment by the Scottish Government in its “Doing Well by People with Depression” programme led to the Doing Well project in Renfrewshire described in this thesis. In 2007, Quality Improvement Scotland introduced integrated care pathways (ICPs) for five conditions including depression.<sup>250</sup> The pathway development group included clinicians from three “Doing Well by People with Depression” areas (including the author). Early learning from the initial evaluation of the “Doing Well by People with Depression” programmes was therefore incorporated into the final Integrated Care Pathway for Depression. The pathways seek to set standards of good practice and then measure variation from that standard by care providers. The condition-specific standards for depression are as follows:

- “There is a record of the offer and uptake of assessment of need, leading to appropriate self-help and signposting within 4 weeks of initial presentation.
- There is a record of the offer and uptake of depression-focused brief psychological therapies within 6 weeks.

- The decision to commence antidepressants/psychological therapy is informed by an objective measure of severity.
- Specialist assessment and treatment is available for service users with treatment resistant, recurrent and chronic depression.”

The emphasis on a comprehensive “assessment of need” (including self-help), the provision of prompt provision of “depression-focused brief psychological therapies” and the use of “objective measures” of depression severity to guide prescribing decisions were closely aligned to the findings of the Doing Well by People with Depression findings reported here and to the findings from other areas.

The author was asked to become the clinical lead for the development of Integrated Care Pathways for Depression in NHS Greater Glasgow and Clyde in early 2008.

### *9.2.2 Health Improvement, Efficiency, Access and Treatment Targets*

Health Improvement, Efficiency, Access and Treatment (“HEAT”) targets are a core set of Ministerial objectives, targets and measures for the NHS. The targets are set for a three year period and progress towards them is measured through the Local Delivery Plan process. In 2007, the Scottish Government introduced a new “HEAT” target to stabilise and then reduce the defined daily doses of antidepressants by the year 2009-10, and to reduce antidepressant use thereafter.<sup>380</sup> This target was supported by a “Mental Health Collaborative” funded by Government. The work of the Collaborative was designed to support the implementation of the Integrated Care Pathway for depression. The author was appointed National Clinical Lead to the depression work of the Collaborative in 2008.



## 10. Appendices

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### 10.1 Grades of evidence

Evidence Grade	SIGN	NICE	Matrix
<b>A</b>	At least one meta-analysis, systematic review, or RCT rated as 1 <sup>++</sup> , and directly applicable to the target population; <i>or</i> A body of evidence consisting principally of studies rated as 1 <sup>+</sup> , directly applicable to the target population, and demonstrating overall consistency of results	At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence level-I) without extrapolation	At least one high quality meta-analysis or systematic review, or RCT of high quality aimed at target population

<b>B</b>	A body of evidence including studies rated as 2 <sup>++</sup> (i.e. High quality systematic reviews of case control or cohort studies, directly applicable to the target population, and demonstrating overall consistency of results; <i>or...</i>	Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation	Well-conducted non randomized clinical studies or RCT of lower quality on the topic of recommendation directly applicable to the target population, and demonstrating overall consistency of results
<b>C</b>	A body of evidence including studies rated as 2 <sup>+</sup> (i.e. well conducted case control or cohort studies with a low risk of confounding or bias, directly applicable to the target population and demonstrating overall consistency of results	Expert committee reports or opinions and/or clinical experiences of respected authorities (evidence level IV). This grading indicates that directly applicable clinical studies of good quality are absent or not readily available	Expert opinions and/or clinical experiences of respected authorities.

## 10.2 Introductory letter



Private & Confidential

Wednesday, 20 October 2004

Dear,

Dr        has referred you to “doing well” for help with depression. I would like to offer you an appointment with myself on

[Date] at [Time]  
at [Surgery]

We have sent you quite a lot of information with this letter. Inside the folder, you’ll find:

- some information about “doing well” and the way we work
- a general information leaflet about depression
- some questionnaires that will help us understand how your depression is affecting you, and how you progress over the next few weeks
- a form that asks for your permission to use some anonymous information about you to be used to monitor the way we work at “doing well”

We know that some people find this too much to take in all at once. But the more you can read before we meet, the more time we are likely to have to work together on your depression.

It would be especially helpful if you could try to fill in all the questionnaires in the yellow pack. Don’t worry if you can’t do them all.

Please phone or email me if you have any questions- or if the appointment above doesn’t suit you.

Yours sincerely,

### 10.3 Information leaflet about the Doing Well service



## information

#### What is 'Doing Well'?

Depression and low mood are very common problems. Some people recover within a few weeks without any extra help; other people need specialist treatment. 'Doing well' aims to find the right kind of treatment for you.

Taking part in 'doing well' will mean that you get extra help in dealing with low mood or depression. This help might be:

- information about using 'self-help'
- advice and support about coping with depression
- antidepressant medicine
- some combination of all these things

Being referred to 'doing well' should also mean that you:

- have to wait less time before seeing a mental health specialist who can help
- get the kind of treatment that's right for you
- have real choices about the approach you want to take
- are able to meet with someone face-to-face to discuss your problems **Who are we?**

We are a team of staff from various professional backgrounds:

- Lynn Ackland (Assistant Psychologist)
- Stephen McGinness (Psychiatric Nurse, Project Manager)
- Michael Smith (Consultant Psychiatrist)
- Katie-Jane Sutherland (Occupational Therapist)
- Diane Young (Psychiatric Nurse)

Our different backgrounds and skills allow us to offer you a range of treatment options best suited to meet your needs.

#### What happens at my first appointment?

The appointment will normally be at your GP practice. Your GP will have asked you some questions about depression that form part of a 'depression score' on a 'Personal Health Questionnaire' (PHQ).

People who have low scores on the PHQ often need little professional help to recover from their problems. Others who have high scores often need antidepressant medicine and/or talking therapies of different kinds to get well again.

You will meet with a member of staff for 45 minutes initially.

We will then discuss with you what kind of help may suit you best. Generally this might mean meeting with you again, and staying in touch by telephone, email or letter. You may also be offered the opportunity to join a group supporting people with depression.

#### What is Self-Help?

People who have mild/ moderate depression are not usually helped by from treatment from antidepressant drugs. But people often do benefit from learning 'self-help' techniques. 'Doing well' staff can talk you through ways of helping yourself to recover more quickly. We can provide free copies of books and leaflets about recovering from depression, and discuss how they might apply to you. The aim of self-help is to allow you to work in your own time at your own pace.

### Other treatment options

If you have a more severe depression, then it is likely that you may require antidepressant medication in addition to a psychological approach to coping with your depression. We think that it's important that you know the pros and cons about antidepressant medicine; how they work and what potential side effects they have. We'll help you to choose whether you think they are the right treatment for you, and if so the kind of medicine you want to take.

You will also have access to other forms of psychological interventions (talking therapies) which will aim to help you work through ways of dealing with any difficulties you may be having.

### Evaluation

It is important for us to know that 'doing well' is working properly and that people find the programme helpful. In order to check that the programme is working, we would like to collect some information about:

- the people that take part
- how they respond to treatment
- what they think of the service

Any information gathered will be kept anonymous- you would never be able to be personally identified from any of the information we use as part of our evaluation. We will provide more information about this at your first appointment. You can, of course, choose not to take any part in the evaluation.

### Complaints

If you have complaint about the service, care or treatment you receive please contact the project manager Stephen McGinness, in the first instance. This will give us the best chance to put right what has gone wrong and the opportunity to improve our service.

Should the matter not be resolved satisfactorily, then a complaint can be put in writing to the designated complaints officer for an independent review.

The designated complaints officer for the Renfrewshire and Inverclyde area is:

Mr Robert Clark, Complaints officer, NHS Argyll & Clyde,  
Merchiston Hospital, Brookfield, Johnstone, PA5 8TY

Complaints should then be acknowledged within 3 working days and responded to within 20 working days.

**If  
you**

'Doing Well'

Tel: 0141 889 8075

New Sneddon Street Clinic

Email: [info@doingwell.org](mailto:info@doingwell.org)

Paisley

Website: [www.doingwell.org](http://www.doingwell.org)

PA3 2AD

feel you need to speak to someone these may be useful phone numbers:

**BREATHING SPACE:** telephone helpline support

0800 838587 (6pm- 2am)

**FIRST CRISIS:** telephone and personal support for people in crisis in Renfrewshire

0500 829 093 (11am-11pm)

**SAMARITANS** - 08457 909090 (24hours)

**Weblinks:**

Information about depression

[www.rcpsych.ac.uk/info/help/dep/index.asp](http://www.rcpsych.ac.uk/info/help/dep/index.asp)

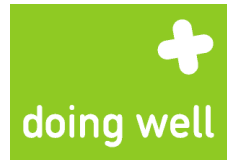
[www.mind.org.uk/Information/Booklets/Understanding/Understanding+depression.htm](http://www.mind.org.uk/Information/Booklets/Understanding/Understanding+depression.htm)

Information about antidepressants

[www.netdoctor.co.uk/medicines/](http://www.netdoctor.co.uk/medicines/)

Stigma and mental health problems

[www.seemescotland.org](http://www.seemescotland.org)



## 10.4 Consent form

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**DW:** Doing Well by People with Depression  
Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE

tel: 0141 884 9085  
fax: 0141 884 9079  
email: [Michael.Smith@renver-pct.scot.nhs.uk](mailto:Michael.Smith@renver-pct.scot.nhs.uk)  
web: [www.renver-pct.scot.nhs.uk](http://www.renver-pct.scot.nhs.uk)



17 March 2004, version 1.1

### Doing Well by People with Depression (DW)

Your doctor has referred you to a new service in Renfrewshire for people with depression. It is called “Doing Well by People with Depression” (DW for short).

Taking part in DW will mean that you get extra help in dealing with your depression. This might be:

- “self-help” support
- advice and support from staff specially trained in helping people with depression
- antidepressant medicine
- or some combination of these things

Someone from the DW team will contact you soon to discuss what kind of help would suit you best. Some people choose a lot of input from the team; others prefer to manage things with little or no support from DWB.

An important part of DW is that we monitor people’s response to depression treatment with a questionnaire called the “Personal Health Questionnaire”, or “PHQ”. You will be shown how to use the PHQ by one of the DWB team.

It is important to us to know that DW is working properly, and that people find the programme helpful. In order to check that the programme is working, we would like to collect some information about the people that take part, how they respond to treatment, and what they think of the service.

This leaflet is to ask your permission to use information about the care you receive while taking part in the DW programme to help us evaluate it. The information used would be anonymous- nobody could identify you from the information we have.

Before you decide whether or not to agree to our use of some anonymised information about your care, it is important for you to understand why the evaluation is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

### **What is the evaluation for?**

DW is meant to help people recover more quickly and more fully from depression. It is also meant to make sure that people only take antidepressant medicine where it is likely to help. We also aim to reduce the waiting time to see specialists in depression, and overall to provide a service that people find more satisfactory than usual GP or specialist care.

In order to make sure we are doing what we seek to do, we need to monitor how the group of people in DWB are doing, and what they think of the new service.

### **Why have I been chosen?**

Everybody with a new episode of depression or low mood who consults their GP in participating GP practices and Health Centres will be offered a referral to DW. We expect that several hundred people will take part as DW becomes available in more practices. Ideally, we would like to include all of these people in the evaluation.

### **Do I have to take part?**

You have a choice about whether or not you want to take part in DW.

If you do take part in DW, you also have a choice about whether or not we can use some of the information about your care in our evaluation of the programme.

If you do decide to let us use some anonymous information about your care in our evaluation, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to let us use this information, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.



### **What will happen to me if I take part?**

Your GP will ask you some questions based on the PHQ, which is a way of measuring how severe people's depression is.

People who have mild depression do not benefit from treatment with antidepressant drugs. Instead of a prescription, your GP will ask if you'd like to be put in contact with a DW staff member who can talk you through ways of helping yourself to recover more quickly. These "self-help support workers" can give you copies of books and leaflets about recovering from depression, and talk you through how they might apply to you. There might be the opportunity to join classes on recovering from depression.

If the PHQ shows that you have more severe depression, then it's likely that antidepressant drugs will help you recover. We think that it's important that you know all about antidepressant medicine, and that you have a choice to take antidepressants or not. To get most benefit from medicine- and talk through any questions or problems you may have- DW can put you in touch with a specialist depression nurse.

If the PHQ shows that you have very severe depression, we will try to get you a prompt appointment with a psychiatrist.

If at any point your depression is not improving as it should, monitoring things with the PHQ will help us to change or increase the kind of treatment you are having.

The DW team will work out of your local GP practice, and will probably see you there. They may be able to visit you at home if that would be helpful. They may also contact you by phone with your permission.

### **What do I have to do?**

All we ask of you is that you use the PHQ questionnaire (yourself, or with DW help) to monitor your progress. If you do not want to take medicine as it is prescribed for you by your GP, we would ask that you let us know about this.

### **What are the alternatives for diagnosis or treatment?**

DWB is best thought of as "enhanced care"- making sure that the kind of care you would usually get from your GP is up to the very best standards.

### **What are the possible disadvantages and risks of taking part?**

We do not think there are any disadvantages or risks to taking part in DWB (see above).

### **What are the possible benefits of taking part?**

DW aims to give you the best possible care for depression.

If you agree to let us use anonymous information in our evaluation, this will help us improve the DW service for other people.

### **When would I stop being part of DWB?**

You would stay in the programme until you recover from depression. You would be free to leave the programme (and continue to have care from your GP) at any time.

### **What if something goes wrong?**

If you have any complaints about DWB, you should inform the programme manager, Stephen McGinness, in the first instance at the phone numbers or address above.

There are no special compensation arrangements if you should be harmed in some way by taking part in the evaluation. However, if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.'

### **Will my taking part in this study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

Your GP will be kept fully informed about your participation in DW.

### **What will happen to the results of the evaluation?**

The results of the evaluation will be used by the DW team to monitor and modify the kind of care we provide to people with depression. It will also be used to report on the progress of DWB to senior managers within NHS Argyll and Clyde, the Scottish Executive and academic doctors at Glasgow University. Aspects of the evaluation may be published in clinical journals or in a postgraduate thesis by Dr Michael Smith supervised at the University of Glasgow. Interested participants would be able to obtain a copy of any of these publications.

Nobody participating in DW will be identified in any report or publication.

#### **Who is organising and funding the evaluation?**

DWB is funded by the Scottish Executive Health Department; some future costs may be covered by NHS Argyll & Clyde. There is no payment to any doctor or staff member for including people in the DW programme.

#### **Who has reviewed the evaluation?**

The evaluation has been reviewed and approved by the Research Ethics Committee in NHS Argyll & Clyde.

#### **Contact for Further Information**

Please contact Stephen McGinness or Dr Michael Smith at the number above if you have any questions about the evaluation or DW more generally.

*Thankyou for agreeing to take part in the evaluation. A copy of the information sheet and your signed consent form will be given to you to keep.*

**DW: Doing Well by People with Depression**  
Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE

tel: 0141 884 9085  
fax: 0141 884 9079  
eml: [Michael.Smith@renver-pct.scot.nhs.uk](mailto:Michael.Smith@renver-pct.scot.nhs.uk)  
[Stephen.McGinness@renver-pct.scot.nhs.uk](mailto:Stephen.McGinness@renver-pct.scot.nhs.uk)  
web: [www.renver-pct.scot.nhs.uk](http://www.renver-pct.scot.nhs.uk)



Centre Number:  
Study Number:  
Patient Identification Number for this evaluation:

## CONSENT FORM

Title of Project: **Evaluation of Doing Well by People with Depression.**  
Name of Researcher: **Dr Michael Smith**

Please  
initial  
box

I confirm that I have read and understand the information sheet dated 17 March 2004 (version 1.1) for the above study and have had the opportunity to ask questions.

☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

☐

I understand that sections of any of my medical notes may be looked at by responsible individuals from NHS Argyll & Clyde. I give permission for these individuals to have access to my records.

☐

I agree to take part in the above study.

☐

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

## 10.5 Assessment instruments



### Before your appointment...

Inside this pack are three sets of questions that will help us understand more about how depression has affected you. They may also help to clarify particular areas or feelings that you are having problems with, and we can discuss this at your appointment.

Please try to complete the questionnaires before you come to your appointment with us. Take your time to read the questions over, and answer honestly. You may want to get help from someone if you find them difficult. Please bring the completed questionnaires with you to your appointment.

It's OK if you're not able to fill in the questions, or would prefer not to.

Thankyou

Your  
name

date


# 1. How has depression affected your thoughts and feelings?

Filling in this “Patient Health Questionnaire” (PHQ) will help us understand how your depression affects you now. It also lets you monitor how your mood changes in the next few weeks.

Thinking about the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day	Score
	0	1	2	3	
1 Little interest or pleasure in doing things.					
2 Feeling down, depressed, or hopeless.					
3 Trouble falling or staying asleep, or sleeping too much.					
4 Feeling tired or having little energy.					
5 Poor appetite or overeating.					
6 Feeling bad about yourself—or that you are a failure or have let yourself or your family down.					
7 Trouble concentrating on things, such as reading the newspaper or watching television.					
8 Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual.					
9 Thoughts that you would be better off dead, or of hurting yourself in some way.					
Total					

2. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all      Somewhat difficult      Very difficult      Extremely difficult

0 0 0 0

Total number of symptoms

Total score

PHQ © Pfizer Inc; reproduced with permission

## 2. How has depression affected your everyday activities?

---

This “work and social adjustment scale” gives an indication of how your depression has affected you in your daily life.

Please rate each of the following questions on a 0 to 8 scale:  
indicates no impairment or problems at all and 8 indicates very severe impairment or problems.

1. Because of the way I feel, my ability to work is impaired

0	1	2	3	4	5	6	7	8	points
Not at all impaired								Very severely impaired	<input type="text"/>

2. Because of the way I feel, my home management (cleaning, tidying, shopping, cooking, looking after home or children, paying bills) is impaired

0	1	2	3	4	5	6	7	8	
Not at all impaired								Very severely impaired	<input type="text"/>

3. Because of the way I feel, my social leisure activities (with other people, such as parties, bars, clubs, outings, visits, dating, home entertainment) are impaired.

0	1	2	3	4	5	6	7	8	
Not at all impaired								Very severely impaired	<input type="text"/>

4. Because of the way I feel, my private leisure activities (done alone, such as reading, gardening, collecting, sewing, walking alone) are impaired.

0	1	2	3	4	5	6	7	8	
Not at all impaired								Very severely impaired	<input type="text"/>

5. Because of the way I feel, my ability to form and maintain close relationships with others, including those I live with is impaired

0	1	2	3	4	5	6	7	8	
Not at all impaired								Very severely impaired	<input type="text"/>

---



TOTAL	<input type="text"/>
-------	----------------------

### 3. How would you rate your quality of life just now?

---

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

#### **Mobility**

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

#### **Self-Care**

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

#### **Usual Activities** (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

#### **Pain/Discomfort**

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

#### **Anxiety/Depression**

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own  
health state**

Best  
imaginable

100

90

80

70

60

50

40

30

20

10

0

Worst

imaginable

## 10.6 Information and confidentiality

The following information was gathered at each visit, and recorded in *Continuum*, the standard electronic record-keeping system used by South Clyde Mental Health services:

### Patient information from SCI gateway:

Name  
DOB  
Gender  
CHI  
Postal address & postcode  
Phone numbers  
Email

### GP information from SCI gateway:

Name  
Surgery  
GP contact phone/email  
Problem list  
Current medication  
PHQ score (all 9 fields)

### 'Doing Well' visit 1 (Assessment):

"Doing Well" worker name  
Date, place of contact  
Record whether attended  
Register consent obtained  
PHQ score as above  
EQ-5D score (5 items) and WSAS  
Antidepressant taken and concordance  
Free text to record other info as relevant

### Subsequent 'Doing Well' visits:

"Doing Well" worker name  
Date, place of contact  
Type of contact  
Record whether attended  
PHQ score as above  
Antidepressant taken and concordance  
Intervention Type (face-to-face contact or phone or email contact)  
Free text to record other info as relevant

### Final 'Doing Well' visit:

"Doing Well" worker name  
Date, place of contact  
Record whether attended  
Reason for discharge  
Discharged to...

PHQ score and WSAS

Antidepressant taken

Free text to record other info as relevant

**Database reports**

Discharge letter

Audit and evaluation measures

Caseload list

## 10.7 Care protocol for self-help support workers

### Self-Help Support Worker: outline care protocol

NB Patient needs, preferences, and progress with self-help, medicine or CBT approaches determined the actual number and nature of contacts.

#### **Contact 1 (face to face, 40- 60mins):**

Explain outline of first session and time allocated, and the purpose the sessions.  
Emphasise flexibility and responsiveness of joint plan.  
Review the information pack and respond to any questions  
Review the GP referral with patient, checking information held is correct  
Assessment of presenting problems and relevant history including drug and alcohol use and present and past medication.  
Repeat PHQ with patient, ensuring that the patient can complete it themselves  
Complete EQ-5D and WSAS  
Discuss intervention and discuss group work if appropriate  
Introduce '5 Areas Approach' & select relevant self help chapters.  
Give brief description of causes, incidence and symptoms of depressive disorders, where appropriate and discuss educational/ informational materials.  
Guide patient in the use of the self help materials  
Explain the protocol for telephone contact  
Discuss evaluation and seek consent for information use. Record written consent where this is obtained.  
Liaise with family and carers as appropriate  
Close and arrange second contact  
Record relevant information on Torex

#### **Any further face to face contact (20-30 mins):**

Review mood, circumstances, PHQ\*  
Review previous session's self help materials  
Joint work on further SH chapters as appropriate  
Any physical difficulties reported should be recorded and referred back to GP in the first instance  
Close and arrange third contact  
If telephone contact arrange a suitable time  
Record relevant information on Torex

#### **Any telephone contact (10-15 mins):**

Review mood, circumstances  
Review previous session and progress with self help materials  
'Encouragement and activation' where appropriate  
If majority of contact is via telephone patients should be able to complete PHQ and inform staff of score at time of telephone contact  
Record contact on Torex

#### **Final contact (face to face, 20-40 minutes):**

Review mood, circumstances, PHQ\*, WSAS  
Review previous session's self help materials  
Joint work on further self help chapters as appropriate  
Decide whether input can be stopped. If no, repeat this session in future contacts.  
Discuss in supervision

If this is the final contact give patient discharge letter and CSQ\*\*  
Record relevant information on Torex

\* Failure to progress as measured by PHQ may be an indication for a different kind of intervention; record and discuss with clinical supervisor.

\*\*CSQ will be given to patients with a self-addressed envelope to complete and post back to the project base.

## 10.8 Care protocol for primary care liaison workers

### Primary Care Liaison Worker: outline care protocol

NB Patient needs, preferences, and progress with self-help, medicine or CBT approaches determined the actual number and nature of contacts.

#### Contact 1 (face to face, 40-60 mins):

Explain outline of first session, and purpose of sessions. Emphasise flexibility and responsiveness of joint plan.

Review information pack, respond to any questions

Review GP referral with patient, checking information held is correct

Comprehensive mental health assessment including antidepressant therapy.

Fill in antidepressant side effect tool, where appropriate and engage patient in education including antidepressant issues- purpose, effects, potential adverse effects and concordance.

Repeat PHQ with patient, ensuring they can complete it themselves

Complete WSAS and EQ-5D

Discuss with patient and jointly decide the most appropriate intervention.

Introduce '5 Areas Approach' & select relevant self help chapters

Give brief description of causes, incidence and symptoms of depressive disorders, where appropriate.

A CBT framework of care will be adopted as model of choice for any interventions.

Guide patient in use of self help materials

Refer to 'Doing well' group work if appropriate

Explain protocol for telephone contact

Discuss evaluation and seek consent for information use. Record written consent where this is obtained

Liaise with family/carers as appropriate

Close and arrange second contact

Record relevant information on Torex

#### Any telephone contact (10-15 mins):

Review mood, circumstances

Review previous session re medicine, concordance, adverse effects, SH materials, CBT etc.; joint work on these issues as appropriate

'Encouragement and activation' where appropriate

If majority of contact is via telephone patients should be able to complete PHQ and inform staff of score at time of telephone contact

Record relevant information on Torex

#### Subsequent face to face contacts (type and duration flexible):

Review mood, circumstances, PHQ\*

Review previous session re medicine, self help materials, CBT etc.; joint work on these issues as appropriate

Side effect tool

Continue education and discussion on concordance issues.

Any physical difficulties reported should be recorded and referred back to G.P in the first instance

Close and arrange subsequent contact

Record relevant information on Torex.

#### Final contact (face to face, 20-40 minutes):



Review mood, circumstances, PHQ\*, WSAS

Review previous session re medicine, self help materials, CBT etc.; joint work on these issues as appropriate

Prepare/continue relapse prevention plan

Give patient discharge letter and CSQ\*\*

Close session

Record relevant information on Torex

\* Failure to progress as measured by PHQ may be an indication for a different kind of intervention; record and discuss with clinical supervisor.

\*\*CSQ will be given to patients with a self-addressed envelope to complete and post back to the project base

## 10.9 Clinical examples

The following examples of clinical cases were prepared by Doing Well service users with the help of a professional writer, and published with their permission on the Doing Well website at [www.doingwell.org.uk](http://www.doingwell.org.uk)

### *10.9.1 Depression can be physical, as well as mental: **Martin, 59***

"I've been a hillwalker all my life. To climb something like Ben Lomond, usually takes me just seven hours or so - that's going up and getting back down again. It's about the equivalent of ten miles on level ground and until last year I could do it as quickly as I could in my twenties.

But right now the most I can walk is about a mile and that leaves me exhausted. In the summer I went to visit family abroad and I wasn't even strong enough to walk between the airport terminals. I needed to get someone to push me in a wheelchair.

The doctors assure me there are no physical reasons for this. I collapsed at work about 7 months ago as a result of stress at work and this in turn caused me to suffer from depression. The depression affected me mentally and physically. I'm getting better, but my body is no where near back to what it was - I get tired very easily. I miss the hills, but the way one doctor put it to me was this: it's as if my body is telling me that it needs a complete rest.

I found the workbooks Doing Well gave me extremely helpful. I can see how some people find them daunting – they are like booklets, as much as ten pages long. I was handed my first one and I groaned because I'm a slow reader anyway. You do need to take the time over them but they really got me looking at things. You see yourself in different situations, and you start to work through the things that apply to you."

*10.9.2 Antidepressants: Lorraine, 44*

"When Doing Well suggested I take anti-depressants I knew I couldn't go on as I was because I was in a downward spiral.

"It was a surprise to me how well they worked - the improvement has been tremendous.

"Now, I'm not bursting into tears every five minutes. I'm getting up in the morning. I'm coping with my work. I'm enjoying my work. I look forward to seeing my students, and I do my prep work at night - but a few months ago you'd have to drag me over hot coals to get me to do that. I'm enjoying life again.

"I do still feel there is a stigma to it though. Even now there are very few people who know I am on anti-depressants. People see the difference in me: they see I'm looking happier but I'm not happy saying it's because I'm on the anti-depressants.

"My husband doesn't know I'm on them, my children don't know I'm on them either. In a way I feel I've let myself down by taking them and that's something I have to deal with in the future.

"I knew I had to take them to give myself a chance. Then after a while- about six weeks in my case - I woke up in the morning and realised I wasn't feeling terrible anymore.

"My situation hasn't changed over the last three months - it is the same as it was. But now I feel I can cope with it."

Lastly, I had the option to participate in the 'doing well' service at my GPs surgery. What a great idea!

### *10.9.3 Doing Well and antidepressants: Joanne, 33y*

"the effect of therapy really surprised me..."

I'm a doctor myself and I think that made me feel sceptical about the idea of going to see a therapist at the Doing Well clinic. I just thought I wouldn't hear anything I didn't already know.

I had a twelve year relationship, from university through my 20s, which wasn't going anywhere, and I was at an age – I'm 33 - where I felt I should be settling down, but wasn't.

I knew the anti-depressants would get me through the low feeling I had – I have used them before - and give me a chance to get myself together. But the effect of the therapy really surprised me.

I started to feel a lot better very quickly - so quickly I knew it couldn't have been down to the drugs. Essentially, here was another healthcare professional reassuring me that what I was feeling was a genuinely problem.

I have a lot of friends to talk to, and family, but I often felt I was whingeing by talking to them about this sort of thing, that I was just making an unnecessary fuss.

But here was another professional telling me I wasn't just making a fuss, that the problems I felt I had were real. That was of enormous help to me from the start, and the lift really surprised me.

One of the things I was concerned about was that the cycle of depressions would leave a permanent mark on me – this was who I now was. The therapist has helped reassure me that this was not the case and I feel more confident now of my own personality and individuality.

I'm also a more philosophical person now. Recently, another relationship came to an end, with a different partner, and it really wasn't as traumatic as I'd have expected it would be. I felt a dip, but I've recovered, and for me that is a huge leap forward.

#### *10.9.4 "I've learned to know how much I can cope with": **Gerry, 52y***

I'd challenge anyone to say they'd got lower than me. I suffered six deaths in quick succession, people from different generations, including a young cousin who died in their early 20s and my girlfriend.

I'd not worked for a couple of years while I was looking after her, and then I found myself on my own, with no where to stay – because the flat had been in her name - and ostracised from my girlfriend's family because they just didn't want to know me.

This was over ten years ago: I drove into a lay-by, I connected the exhaust pipe to the car cabin and I was ready to end it there and then. But I didn't, I decided to go for help, instead.

I walked into the social work department and asked to see someone. They were very polite, I explained what I'd been going through for ten minutes, but then they told me 'sorry, we've no one qualified to deal with you.'

I tried another couple of places too, but there was nothing quite right – and I didn't want to go on drugs but I went to the doctor and she suggested I use beta blockers. They keep me calm. The next thing I did was buy a caravan and head south. I spent a year walking along a beach. This was my time off work, if you like. It helped me get myself together and when I came back north.

I retrained in desktop publishing and that's led to a couple of jobs, but I've left those on my own – I have other health problems too – but as Clint Eastwood said: 'A man's got to know his own limitations.' I've learned to know how much I can cope with, and if I'm within those boundaries I can deal with the day to day.

Going to Doing Well, has helped in that. Therapy has given me someone to talk to, someone who knows what they are talking about, but who isn't in your immediate family. I just wish they'd been around ten years ago, because I really needed them then.

#### *10.9.5 "I'd just think people were being self indulgent": **Barbara, 41***

One evening I was on the way home and I very nearly crashed my car. I was driving at about 60mph on the motorway, on a route I took almost every day, but I all I was thinking about was my job because I was juggling five or six projects. I went to change lanes and almost hit someone else - I was clearly in the wrong.

That night I didn't sleep – I realised things had to change. The next day I couldn't face work because I felt like it had almost cost me my life.

I went to see my GP and that was when I did my PHQ – the score was really high. Alarmingly high, actually.

At the Doing Well clinic I used the workbooks and met up with the therapist. It was really good for me to have someone who wasn't work related or family to talk to. It was like getting a neutral opinion of my life. It's helped me understand how I was feeling and what led to it.

You know, before this I never really believed in depression. I actually had a close friend who suffered from it but I would be like 'oh just pull yourself together'. It sounds terrible thinking about it now, but that is what I used to think. I didn't see it as a real thing I'd just think people were being self indulgent.

I took two and a half months off work and since then I've actually changed my job. I was completely honest with my new employer at the interview and they've been great about it. Things have been going really well, I'm not taking on too much, and I'm realising there is more to life than just work.

## 11. References

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